

*The*  
**NORTH CAROLINA  
REGISTER**

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# INFORMATION ABOUT THE NORTH CAROLINA REGISTER AND ADMINISTRATIVE CODE

## NORTH CAROLINA REGISTER

The *North Carolina Register* is published twice a month and contains information relating to agency, executive, legislative and judicial actions required by or affecting Chapter 150B of the General Statutes. All proposed administrative rules and notices of public hearings filed under G.S. 150B-21.2 must be published in the Register. The Register will typically comprise approximately fifty pages per issue of legal text.

State law requires that a copy of each issue be provided free of charge to each county in the state and to various state officials and institutions.

The *North Carolina Register* is available by yearly subscription at a cost of one hundred and five dollars (\$105.00) for 24 issues. Individual issues may be purchased for eight dollars (\$8.00).

Requests for subscription to the *North Carolina Register* should be directed to the Office of Administrative Hearings, P. O. Drawer 27447, Raleigh, N. C. 27611-7447.

## ADOPTION AMENDMENT, AND REPEAL OF RULES

The following is a generalized statement of the procedures to be followed for an agency to adopt, amend, or repeal a rule. For the specific statutory authority, please consult Article 2A of Chapter 150B of the General Statutes.

Any agency intending to adopt, amend, or repeal a rule must first publish notice of the proposed action in the *North Carolina Register*. The notice must include the time and place of the public hearing (or instructions on how a member of the public may request a hearing); a statement of procedure for public comments; the text of the proposed rule or the statement of subject matter; the reason for the proposed action; a reference to the statutory authority for the action and the proposed effective date.

Unless a specific statute provides otherwise, at least 15 days must elapse following publication of the notice in the *North Carolina Register* before the agency may conduct the public hearing and at least 30 days must elapse before the agency can take action on the proposed rule. An agency may not adopt a rule that differs substantially from the proposed form published as part of the public notice, until the adopted version has been published in the *North Carolina Register* for an additional 30 day comment period.

When final action is taken, the promulgating agency must file the rule with the Rules Review Commission (RRC). After approval by RRC, the adopted rule is filed with the Office of Administrative Hearings (OAH).

A rule or amended rule generally becomes effective 5 business days after the rule is filed with the Office of Administrative Hearings for publication in the *North Carolina Administrative Code* (NCAC).

Proposed action on rules may be withdrawn by the promulgating agency at any time before final action is taken by the agency or before filing with OAH for publication in the NCAC.

## TEMPORARY RULES

Under certain emergency conditions, agencies may issue temporary rules. Within 24 hours of submission to OAH, the Codifier of Rules must review the agency's written statement of findings of need for the temporary rule pursuant to the provisions in G.S. 150B-21.1. If the Codifier determines that the findings meet the criteria in G.S. 150B-21.1, the rule is entered into the NCAC. If the Codifier determines that the findings do not meet the criteria, the rule is returned to the agency. The agency may supplement its findings and resubmit the temporary rule for an additional review or the agency may respond that it will remain with its initial position. The Codifier, thereafter, will enter the rule into the NCAC. A temporary rule becomes effective either when the Codifier of Rules enters the rule in the Code or on the sixth business day after the agency resubmits the rule without change. The temporary rule is in effect for the period specified in the rule or 180 days, whichever is less. An agency adopting a temporary rule must begin rule-making procedures on the permanent rule at the same time the temporary rule is filed with the Codifier.

## NORTH CAROLINA ADMINISTRATIVE CODE

The North Carolina Administrative Code (NCAC) is a compilation and index of the administrative rules of 25 state agencies and 38 occupational licensing boards. The NCAC comprises approximately 15,000 letter size, single spaced pages of material of which approximately 35% of is changed annually. Compilation and publication of the NCAC is mandated by G.S. 150B-21.18.

The Code is divided into Titles and Chapters. Each state agency is assigned a separate title which is further broken down by chapters. Title 21 is designated for occupational licensing boards.

The NCAC is available in two formats.

- (1) Single pages may be obtained at a minimum cost of two dollars and 50 cents (\$2.50) for 10 pages or less, plus fifteen cents (\$0.15) per each additional page.
- (2) The full publication consists of 53 volumes, totaling in excess of 15,000 pages. It is supplemented monthly with replacement pages. A one year subscription to the full publication including supplements can be purchased for seven hundred and fifty dollars (\$750.00). Individual volumes may also be purchased with supplement service. Renewal subscriptions for supplements to the initial publication are available.

Requests for pages of rules or volumes of the NCAC should be directed to the Office of Administrative Hearings.

## CITATION TO THE NORTH CAROLINA REGISTER

The *North Carolina Register* is cited by volume, issue, page number and date. 1:1 NCR 101-201, April 1, 1986 refers to Volume 1, Issue 1, pages 101 through 201 of the *North Carolina Register* issued on April 1, 1986.

FOR INFORMATION CONTACT: Office of  
Administrative Hearings, ATTN: Rules Division, P.O.  
Drawer 27447, Raleigh, North Carolina 27611-7447, (919)  
733-2678.

# NORTH CAROLINA REGISTER



*Office of Administrative Hearings  
P. O. Drawer 27447  
Raleigh, North Carolina 27611-7447  
(919) 733-2678*

Julian Mann III,  
*Director*  
James R. Scarcella Sr.,  
*Deputy Director*  
Molly Masich,  
*Director of APA Services*

Staff:  
Ruby Creech,  
*Publications Coordinator*  
Teresa Kilpatrick,  
*Editorial Assistant*  
Jean Shirley,  
*Editorial Assistant*

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# NORTH CAROLINA REGISTER

## *Publication Schedule*

*(August 1992 - December 1993)*

Issue Date	Last Day for Filing	Last Day for Elec- tronic Filing	Earliest Date for Public Hearing	Earliest Date for Adoption by Agency	Last Day to Submit to RRC	*Earliest Effective Date
*****	*****	*****	*****	*****	*****	*****
08/03/92	07/13/92	07/20/92	08/18/92	09/02/92	09/20/92	11/02/92
08/14/92	07/24/92	07/31/92	08/29/92	09/13/92	09/20/92	11/02/92
09/01/92	08/11/92	08/18/92	09/16/92	10/01/92	10/20/92	12/01/92
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11/02/92	10/12/92	10/19/92	11/17/92	12/02/92	12/20/92	02/01/93
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11/15/93	10/22/93	10/29/93	11/30/93	12/15/93	12/20/93	02/01/94
12/01/93	11/05/93	11/15/93	12/16/93	12/31/93	01/20/94	03/01/94
12/15/93	11/24/93	12/01/93	12/30/93	01/14/94	01/20/94	03/01/94

\* The "Earliest Effective Date" is computed assuming that the agency follows the publication schedule above, that the Rules Review Commission approves the rule at the next calendar month meeting after submission, and that RRC delivers the rule to the Codifier of Rules five (5) business days before the 1st business day of the next calendar month.



## CHAPTER 150B

## THE ADMINISTRATIVE PROCEDURE ACT

[The following excerpt contains the statutory provisions of the Administrative Procedure Act as amended by the 1991 General Assembly, Second Session effective July 1, 1992 and January 1, 1993.]

## Article 1.

## General Provisions.

## § 150B-1. Policy and scope.

(a) Purpose. -- This Chapter establishes a uniform system of administrative rule making and adjudicatory procedures for agencies. The procedures ensure that the functions of rule making, investigation, advocacy, and adjudication are not all performed by the same person in the administrative process.

(b) Rights. -- This Chapter confers procedural rights.

(c) Full Exemptions. -- This Chapter applies to every agency except:

- (1) The North Carolina National Guard in exercising its court-martial jurisdiction.
- (2) The Department of Human Resources in exercising its authority over the Camp Butner reservation granted in Article 6 of Chapter 122C of the General Statutes.
- (3) The Utilities Commission.
- (4) The Industrial Commission.
- (5) The Employment Security Commission.

(d) Exemptions From Rule Making. -- Article 2A of this Chapter does not apply to the following:

- (1) The Commission.
- (2) The North Carolina Low-Level Radioactive Waste Management Authority in administering the provisions of G.S. 104G-10 and G.S. 104G-11.
- (3) The North Carolina Hazardous Waste Management Commission in administering the provisions of G.S. 130B-13 and G.S. 130B-14.
- (4) The Department of Revenue, except that Parts 3 and 4 of Article 2A apply to the Department.
- (5) The North Carolina Air Cargo Airport Authority with respect to the acquisition, construction, operation, or use, including fees or charges, of any portion of a cargo airport complex.

(e) Exemptions From Contested Case Provisions. -- The contested case provisions of this Chapter apply to all agencies and all proceedings not expressly exempted from the Chapter. The

contested case provisions of this Chapter do not apply to the following:

- (1) The Department of Human Resources and the Department of Environment, Health, and Natural Resources in complying with the procedural safeguards mandated by Section 680 of Part H of Public Law 99-457 as amended (Education of the Handicapped Act Amendments of 1986).
- (2) The Governor's Waste Management Board in administering the provisions of G.S. 104E-6.2 and G.S. 130A-293.
- (3) The North Carolina Low-Level Radioactive Waste Management Authority in administering the provisions of G.S. 104G-9, 104G-10, and 104G-11.
- (4) The North Carolina Hazardous Waste Management Commission in administering the provisions of G.S. 130B-11, 130B-13, and 130B-14.
- (5) Hearings required pursuant to the Rehabilitation Act of 1973, (Public Law 93-122), as amended and federal regulations promulgated thereunder. G.S. 150B-51(a) is considered a contested case hearing provision that does not apply to these hearings.
- (6) The Department of Revenue.
- (7) The Department of Correction.
- (8) The Department of Transportation, except as provided in G.S. 136-29.
- (9) The Occupational Safety and Health Review Board in all actions that do not involve agricultural employers.
- (10) The North Carolina Air Cargo Airport Authority with respect to the acquisition, construction, operation, or use, including fees or charges, of any portion of a cargo airport complex.

(f) Exemption From All But Judicial Review. -- No Article in this Chapter except Article 4 applies to the University of North Carolina.

§ 150B-2. Definitions. -- As used in this Chapter,

- (01) "Administrative law judge" means a person appointed under G.S. 7A-752.

- 7A-753, or 7A-757.
- (1) "Agency" means an agency or an officer in the executive branch of the government of this State and includes the Council of State, the Governor's Office, a board, a commission, a department, a division, a council, and any other unit of government in the executive branch. A local unit of government is not an agency.
  - (1a) "Adopt" means to take final action to create, amend, or repeal a rule.
  - (1b) "Codifier of Rules" means the Chief Administrative Law Judge of the Office of Administrative Hearings or a designated representative of the Chief Administrative Law Judge.
  - (1c) "Commission" means the Rules Review Commission.
  - (2) "Contested case" means an administrative proceeding pursuant to this Chapter to resolve a dispute between an agency and another person that involves the person's rights, duties, or privileges, including licensing or the levy of a monetary penalty. "Contested case" does not include rulemaking, declaratory rulings, or the award or denial of a scholarship or grant.
  - (2a) Repealed.
  - (2b) "Hearing officer" means a person or group of persons designated by an agency that is subject to Article 3A of this Chapter to preside in a contested case hearing conducted under that Article.
  - (3) "License" means any certificate, permit or other evidence, by whatever name called, of a right or privilege to engage in any activity, except licenses issued under Chapter 20 and Subchapter 1 of Chapter 105 of the General Statutes and occupational licenses.
  - (4) "Licensing" means any administrative action issuing, failing to issue, suspending, or revoking a license or occupational license. "Licensing" does not include controversies over whether an examination was fair or whether the applicant passed the examination.
  - (4a) Occupational license" means any certificate, permit, or other evidence, by whatever name called, of a right or privilege to engage in a profession, occupation, or field of endeavor that is issued by an occupational licensing agency.
  - (4b) "Occupational licensing agency" means any board, commission, committee or other agency of the State of North Carolina which is established for the primary purpose of regulating the entry of persons into, and/or the conduct of persons within a particular profession, occupation or field of endeavor, and which is authorized to issue and revoke licenses. "Occupational licensing agency" does not include State agencies or departments which may as only a part of their regular function issue permits or licenses.
  - (5) "Party" means any person or agency named or admitted as a party or properly seeking as of right to be admitted as a party and includes the agency as appropriate. This subdivision does not permit an agency that makes a final decision, or an officer or employee of the agency, to petition for initial judicial review of that decision.
  - (6) "Person aggrieved" means any person or group of persons of common interest directly or indirectly affected substantially in his or its person, property, or employment by an administrative decision.
  - (7) "Person" means any natural person, partnership, corporation, body politic and any unincorporated association, organization, or society which may sue or be sued under a common name.
  - (8) "Residence" means domicile or principal place of business.
  - (8a) "Rule" means any agency regulation, standard, or statement of general applicability that implements or interprets an enactment of the General Assembly or Congress or a regulation adopted by a federal agency or that describes the procedure or practice requirements of an agency. The term includes the establishment of a fee and the amendment or repeal of a prior rule. The term does not include the following:
    - a. Statements concerning only the internal management of an agency or group of agencies within the same principal office or department enumerated in G.S. 143-11 or 143B-6, including policies and

- procedures manuals, if the statement does not directly or substantially affect the procedural or substantive rights or duties of a person not employed by the agency or group of agencies.
- b. Budgets and budget policies and procedures issued by the Director of the Budget, by the head of a department, as defined by G.S. 143A-2 or G.S. 143B-3, by an occupational licensing board, as defined by G.S. 93B-1, or by the State Board of Elections.
  - c. Nonbinding interpretive statements within the delegated authority of an agency that merely define, interpret, or explain the meaning of a statute or rule.
  - d. A form, the contents or substantive requirements of which are prescribed by rule or statute.
  - e. Statements of agency policy made in the context of another proceeding, including:
    1. Declaratory rulings under G.S. 150B-4.
    2. Orders establishing or fixing rates or tariffs.
  - f. Requirements, communicated to the public by the use of signs or symbols, concerning the use of public roads, bridges, ferries, buildings, or facilities.
  - g. Statements that set forth criteria or guidelines to be used by the staff of an agency in performing audits, investigations, or inspections; in settling financial disputes or negotiating financial arrangements; or in the defense, prosecution, or settlement of cases.
  - h. Scientific, architectural, or engineering standards, forms, or procedures, including design criteria and construction standards used to construct or maintain highways, bridges, or ferries.
  - i. Job classification standards, job qualifications, and salaries established for positions under the jurisdiction of the State Personnel Commission.
  - j. Establishment of the interest rate that applies to tax assessments

under G.S. 105-241.1 and the variable component of the excise tax on motor fuel under G.S. 105-434.

- (8b) "Substantial evidence" means relevant evidence a reasonable mind might accept as adequate to support a conclusion.

- (9) Repealed.

#### § 150B-3. Special provisions on licensing.

(a) When an applicant or a licensee makes a timely and sufficient application for issuance or renewal of a license or occupational license, including the payment of any required license fee, the existing license or occupational license does not expire until a decision on the application is finally made by the agency, and if the application is denied or the terms of the new license or occupational license are limited, until the last day for applying for judicial review of the agency order. This subsection does not affect agency action summarily suspending a license or occupational license under subsections (b) and (c) of this section.

(b) Before the commencement of proceedings for the suspension, revocation, annulment, withdrawal, recall, cancellation, or amendment of any license other than an occupational license, the agency shall give notice to the licensee, pursuant to the provisions of G.S. 150B-23. Before the commencement of such proceedings involving an occupational license, the agency shall give notice pursuant to the provisions of G.S. 150B-38. In either case, the licensee shall be given an opportunity to show compliance with all lawful requirements for retention of the license or occupational license.

(c) If the agency finds that the public health, safety, or welfare requires emergency action and incorporates this finding in its order, summary suspension of a license or occupational license may be ordered effective on the date specified in the order or on service of the certified copy of the order at the last known address of the licensee, whichever is later, and effective during the proceedings. The proceedings shall be promptly commenced and determined.

Nothing in this subsection shall be construed as amending or repealing any special statutes, in effect prior to February 1, 1976, which provide for the summary suspension of a license.

#### § 150B-4. Declaratory rulings.

(a) On request of a person aggrieved, an agency shall issue a declaratory ruling as to the validity of a rule or as to the applicability to a given state of

facts of a statute administered by the agency or of a rule or order of the agency, except when the agency for good cause finds issuance of a ruling undesirable. The agency shall prescribe in its rules the circumstances in which rulings shall or shall not be issued. A declaratory ruling is binding on the agency and the person requesting it unless it is altered or set aside by the court. An agency may not retroactively change a declaratory ruling, but nothing in this section prevents an agency from prospectively changing a declaratory ruling. A declaratory ruling is subject to judicial review in the same manner as an order in a contested case. Failure of the agency to issue a declaratory ruling on the merits within 60 days of the request for such ruling shall constitute a denial of the request as well as a denial of the merits of the request and shall be subject to judicial review.

(b) This section does not apply to the Department of Correction.

#### Article 2.

#### Rule Making.

#### Repealed.

#### Article 2A.

#### Rules.

#### Part 1. General Provisions.

### § 150B-18. Scope and effect.

This Article applies to an agency's exercise of its authority to adopt a rule. A rule is not valid unless it is adopted in substantial compliance with this Article.

### § 150B-19. Restrictions on what can be adopted as a rule.

An agency may not adopt a rule that does one or more of the following:

- (1) Implements or interprets a law unless that law or another law specifically authorizes the agency to do so.
- (2) Enlarges the scope of a profession, occupation, or field of endeavor for which an occupational license is required.
- (3) Imposes criminal liability or a civil penalty for an act or omission, including the violation of a rule, unless a law specifically authorizes the agency to do so or a law declares that violation of the rule is a criminal offense or is grounds for a civil penalty.
- (4) Repeats the content of a law, a rule, or a federal regulation.
- (5) Establishes a reasonable fee or other reasonable charge for providing a service in fulfillment of a duty unless a

law specifically authorizes the agency to do so or the fee or other charge is for one of the following:

- a. A service to a State, federal, or local governmental unit.
- b. A copy of part or all of a State publication or other document, the cost of mailing a document, or both.
- c. A transcript of a public hearing.
- d. A conference, workshop, or course.
- e. Data processing services.
- (6) Allows the agency to waive or modify a requirement set in a rule unless a rule establishes specific guidelines the agency must follow in determining whether to waive or modify the requirement.

### § 150B-20. Petitioning an agency to adopt a rule.

(a) Petition. -- A person may petition an agency to adopt a rule by submitting to the agency a written rule-making petition requesting the adoption. A person may submit written comments with a rule-making petition. If a rule-making petition requests the agency to create or amend a rule, the person must submit the proposed text of the requested rule change and a statement of the effect of the requested rule change. Each agency must establish by rule the procedure for submitting a rule-making petition to it and the procedure the agency follows in considering a rule-making petition.

(b) Time. -- An agency must grant or deny a rule-making petition submitted to it within 30 days after the date the rule-making petition is submitted, unless the agency is a board or commission. If the agency is a board or commission, it must grant or deny a rule-making petition within 120 days after the date the rule-making petition is submitted.

(c) Action. -- If an agency denies a rule-making petition, it must send the person who submitted the petition a written statement of the reasons for denying the petition. If an agency grants a rule-making petition, it must inform the person who submitted the rule-making petition of its decision and must initiate rule-making proceedings. When an agency grants a rule-making petition requesting the creation or amendment of a rule, the notice of rule making it publishes in the North Carolina Register may state that the agency is initiating rule-making proceedings as the result of a rule-making petition, state the name of the person who submitted the rule-making petition, set out the text of the requested rule change submitted with the rule-making petition, and state whether the agency endorses the proposed rule change.

(d) Review. -- Denial of a rule-making petition is a final agency decision and is subject to judicial review under Article 4 of this Chapter. Failure of an agency to grant or deny a rule-making petition within the time limits set in subsection (b) is a denial of the rule-making petition.

(e) Exception. -- This section does not apply to the Department of Correction.

**§ 150B-21. Agency must designate rule-making coordinator.**

Each agency must designate one or more rule-making coordinators to oversee the agency's rule-making functions. The coordinator must prepare notices of public hearings, coordinate access to the agency's rules, and serve as the liaison between the agency, other agencies, and the public in the rule-making process.

**Part 2. Adoption of Rules.**

**§ 150B-21.1. Procedure for adopting a temporary rule.**

(a) Adoption. -- An agency may adopt a temporary rule without prior notice or hearing or upon any abbreviated notice or hearing the agency finds practical when it finds that adherence to the notice and hearing requirements of this Part would be contrary to the public interest and that the immediate adoption of the rule is required by one or more of the following:

- (1) A serious and unforeseen threat to the public health, safety, or welfare.
- (2) The effective date of a recent act of the General Assembly or the United States Congress.
- (3) A recent change in federal or State budgetary policy.
- (4) A federal regulation.
- (5) A court order.
- (6) The need for the rule to become effective the same date as the State Medical Facilities Plan approved by the Governor, if the rule addresses a matter included in the State Medical Facilities Plan.

An agency must prepare a written statement of its findings of need for a temporary rule. The statement must be signed by the head of the agency adopting the rule.

An agency must begin rule-making proceedings for a permanent rule by the day it adopts a temporary rule. An agency begins rule-making proceedings for a permanent rule by submitting to the codifier written notice of its intent to adopt a permanent rule.

(b) Review. -- When an agency adopts a temporary rule it must submit the rule, the agency's

written statement of its findings of need for the rule, and the notice of intent to adopt a permanent rule to the Codifier of Rules. Within one business day after an agency submits a temporary rule, the Codifier of Rules must review the agency's written statement of findings of need for the rule to determine whether the statement of need meets the criteria listed in subsection (a). In reviewing the statement, the Codifier of Rules may consider any information submitted by the agency or another person. If the Codifier of Rules finds that the statement meets the criteria, the Codifier of Rules must notify the head of the agency and enter the rule in the North Carolina Administrative Code.

If the Codifier of Rules finds that the statement does not meet the criteria, the Codifier of Rules must immediately notify the head of the agency. The agency may supplement its statement of need with additional findings or submit a new statement. If the agency provides additional findings or submits a new statement, the Codifier of Rules must review the additional findings or new statement within one business day after the agency submits the additional findings or new statement. If the Codifier of Rules again finds that the statement does not meet the criteria listed in subsection (a), the Codifier of Rules must immediately notify the head of the agency.

If an agency decides not to provide additional findings or submit a new statement when notified by the Codifier of Rules that the agency's findings of need for a rule do not meet the required criteria, the agency must notify the Codifier of Rules of its decision. The Codifier of Rules must then enter the rule in the North Carolina Administrative Code on the sixth business day after receiving notice of the agency's decision.

(c) Standing. -- A person aggrieved by a temporary rule adopted by an agency may file an action for declaratory judgment in Wake County Superior Court pursuant to Article 26 of Chapter 1 of the General Statutes. In the action, the court shall determine whether the agency's written statement of findings of need for the rule meets the criteria listed in subsection (a) and whether the rule meets the standards in G.S. 150B-21.9 that apply to review of a permanent rule. The court may not grant an *ex parte* temporary restraining order.

Filing a petition for rule making or a request for a declaratory ruling with the agency that adopted the rule is not a prerequisite to filing an action under this subsection. A person who files an action for declaratory judgment under this subsection must serve a copy of the complaint on the agency that adopted the rule being contested, the

Codifier of Rules, and the Commission.

(d) **Effective Date and Expiration.** -- A temporary rule becomes effective on the date specified in G.S. 150B-21.3. A temporary rule expires on the date specified in the rule or 180 days from the date the rule becomes effective, whichever comes first.

**§ 150B-21.2. Procedure for adopting a permanent rule.**

(a) **Notice.** -- Before an agency adopts a permanent rule, it must publish notice of its intent to adopt a permanent rule in the North Carolina Register and as required by any other law. The notice published in the North Carolina Register must include all of the following:

- (1) Either the text of the proposed rule or a statement of the subject matter of the proposed rule making.
- (2) A short explanation of the reason for the proposed action.
- (3) A citation to the law that gives the agency the authority to adopt the proposed rule, if the notice includes the text of the proposed rule, or a citation to the law that gives the agency the authority to adopt a rule on the subject matter of the proposed rule making, if the notice includes only a statement of the subject matter of the proposed rule making.
- (4) The proposed effective date of the proposed rule, if the notice includes the text of the proposed rule, or the proposed effective date of a rule adopted on the subject matter of the proposed rule making, if the notice includes only a statement of the subject matter of the proposed rule making.
- (5) The date, time, and place of any public hearing scheduled on the proposed rule or subject matter of the proposed rule making.
- (6) Instructions on how a person may demand a public hearing on a proposed rule if the notice does not schedule a public hearing on the proposed rule and subsection (c) requires the agency to hold a public hearing on the proposed rule when requested to do so.
- (7) The period of time during which and the person to whom written comments may be submitted on the proposed rule or subject matter of the proposed rule making.
- (8) If a fiscal note has been prepared for the proposed rule or will be prepared

when a rule is proposed on the subject matter of the proposed rule making, a statement that a copy of the fiscal note can be obtained from the agency.

(b) **Mailing List.** -- An agency must maintain a mailing list of persons who have requested notice of rule making. When an agency publishes a rule-making notice in the North Carolina Register, it must mail a copy of the notice to each person on the mailing list who has requested notice of rule-making proceedings on the rule or the subject matter for rule making described in the notice. An agency may charge an annual fee to each person on the agency's mailing list to cover copying and mailing costs.

(c) **Hearing.** -- An agency must hold a public hearing on a rule it proposes to adopt in two circumstances and may hold a public hearing in other circumstances. When an agency is required to hold a public hearing on a proposed rule or decides to hold a public hearing on a proposed rule when it is not required to do so, the agency must publish in the North Carolina Register a notice of the date, time, and place of the public hearing. The hearing date of a public hearing held after the agency publishes notice of the hearing in the North Carolina Register must be at least 15 days after the date the notice is published.

An agency must hold a public hearing on a rule it proposes to adopt in the following two circumstances:

- (1) The agency publishes a statement of the subject matter of the proposed rule making in the notice in the North Carolina Register.
- (2) The agency publishes the text of the proposed rule in the notice in the North Carolina Register and all the following apply:
  - a. The notice does not schedule a public hearing on the proposed rule.
  - b. Within 15 days after the notice is published, the agency receives a written request for a public hearing on the proposed rule.
  - c. The proposed rule is not part of a rule-making proceeding the agency initiated by publishing a statement of the subject matter of proposed rule making.
  - d. The proposed text is not a changed version of proposed text the agency previously published in the course of rule-making proceedings but did not adopt.

(d) Text After Subject-Matter Notice. -- When an agency publishes notice of the subject matter of proposed rule making in the North Carolina Register, it must subsequently publish in the North Carolina Register the text of the rule it proposes to adopt as a result of the public hearing and of any comments received on the subject matter. An agency may not publish the proposed text of a rule for which it published a subject-matter notice before the public hearing on the subject matter.

(e) Comments. -- An agency must accept comments on the text of a proposed rule published in the North Carolina Register for at least 30 days after the text is published or until the date of any public hearing held on the proposed rule, whichever is longer. An agency must accept comments on a statement of the subject matter of proposed rule making until the public hearing on the subject matter. An agency must consider fully all written and oral comments received.

(f) Adoption. -- An agency may not adopt a rule until the time for commenting on the proposed text of the rule has elapsed and may not adopt a rule if more than 12 months have elapsed since the end of the time for commenting on the proposed text of the rule. An agency may not adopt a rule that differs substantially from the text of a proposed rule published in the North Carolina Register unless the agency publishes the text of the proposed different rule in the North Carolina Register and accepts comments on the proposed different rule for the time set in subsection (e).

An adopted rule differs substantially from a proposed rule if it does one or more of the following:

- (1) Affects the interests of persons who, based on the notice published in the North Carolina Register or the proposed text of the rule, could not reasonably have determined that the rule would affect their interests.
- (2) Addresses a subject matter or an issue that is not addressed in the proposed text of the rule.
- (3) Produces an effect that could not reasonably have been expected based on the proposed text of the rule.

When an agency adopts a rule, it may not take subsequent action on the rule without following the procedures in this Part.

(g) Explanation. -- An agency must issue a concise written statement explaining why the agency adopted a rule if, within 30 days after the agency adopts the rule, a person asks the agency to do so. The explanation must state the principal

reasons for and against adopting the rule and must discuss why the agency rejected any arguments made or considerations urged against the adoption of the rule.

(h) Record. -- An agency must keep a record of a rule-making proceeding. The record must include all written comments received, a transcript or recording of any public hearing held on the rule, and any written explanation made by the agency for adopting the rule.

#### § 150B-21.3. Effective date of rules.

(a) Temporary Rule. -- A temporary rule becomes effective on the date the Codifier of Rules enters the rule in the North Carolina Administrative Code.

(b) Permanent Rule. -- A permanent rule approved by the Commission becomes effective five business days after the Commission delivers the rule to the Codifier of Rules, unless the agency adopting the rule specifies a later effective date. If the agency specifies a later effective date, the rule becomes effective on that date.

A permanent rule that is not approved by the Commission becomes effective five business days after the agency adopting the rule delivers the rule to the Codifier of Rules, unless the agency adopting the rule specifies a later effective date. If the agency specifies a later effective date, the rule becomes effective on that date.

(c) OSHA Standard. -- A permanent rule concerning an occupational safety and health standard that is adopted by the Occupational Safety and Health Division of the Department of Labor and is identical to a federal regulation promulgated by the Secretary of the United States Department of Labor becomes effective on the date the Division delivers the rule to the Codifier of Rules, unless the Division specifies a later effective date. If the Division specifies a later effective date, the rule becomes effective on that date.

#### § 150B-21.4. Fiscal notes on rules.

(a) State Funds. -- Before an agency publishes in the North Carolina Register the proposed text of a permanent rule change that would require the expenditure or distribution of funds subject to the Executive Budget Act, Article 1 of Chapter 143, it must submit the text of the proposed rule change and a fiscal note on the proposed rule change to the Director of the Budget and obtain certification from the Director that the funds that would be required by the proposed rule change are available. The fiscal note must state the amount of funds that would be expended or distributed as a result of the proposed rule change and explain how the amount was computed. The Director of the Budget must

certify a proposed rule change if funds are available to cover the expenditure or distribution required by the proposed rule change.

(b) Local Funds. -- Before an agency publishes in the North Carolina Register the proposed text of a permanent rule change that would affect the expenditures or revenues of a unit of local government, it must submit the text of the proposed rule change and a fiscal note on the proposed rule change to the Fiscal Research Division of the General Assembly, the Office of State Budget and Management, the North Carolina Association of County Commissioners, and the North Carolina League of Municipalities. The fiscal note must state the amount by which the proposed rule change would increase or decrease expenditures or revenues of a unit of local government and must explain how the amount was computed.

(c) Errors. -- An erroneous fiscal note prepared in good faith does not affect the validity of a rule.

**§ 150B-21.5. Circumstances when notice and rule-making hearing not required.**

(a) Amendment. -- An agency is not required to publish a notice of rule making in the North Carolina Register or hold a public hearing when it proposes to amend a rule, without changing the substance of the rule, to do one of the following:

- (1) Reletter or renumber the rule or subparts of the rule.
- (2) Substitute one name for another when an organization or position is renamed.
- (3) Correct a citation in the rule to another rule or law when the citation has become inaccurate since the rule was adopted because of the repeal or renumbering of the cited rule or law.
- (4) Change information that is readily available to the public, such as an address or a telephone number.
- (5) Correct a typographical error made in entering the rule in the North Carolina Administrative Code.
- (6) Change a rule in response to a request or an objection by the Commission.

(b) Repeal. -- An agency is not required to publish a notice of rule making in the North Carolina Register or hold a public hearing when it proposes to repeal a rule as a result of any of the following:

- (1) The law under which the rule was adopted is repealed.
- (2) The law under which the rule was adopted or the rule itself is declared unconstitutional.
- (3) The rule is declared to be in excess of

the agency's statutory authority.

(c) OSHA Standard. -- The Occupational Safety and Health Division of the Department of Labor is not required to publish a notice of rule making in the North Carolina Register or hold a public hearing when it proposes to adopt a rule that concerns an occupational safety and health standard and is identical to a federal regulation promulgated by the Secretary of the United States Department of Labor. The Occupational Safety and Health Division is not required to submit to the Commission for review a rule for which notice and hearing is not required under this subsection.

**§ 150B-21.6. Incorporating material in a rule by reference.**

An agency may incorporate the following material by reference in a rule without repeating the text of the referenced material:

- (1) Another rule or part of a rule adopted by the agency.
- (2) All or part of a code, standard, or regulation adopted by another agency, the federal government, or a generally recognized organization or association.
- (3) Material adopted to meet a requirement of the federal government.

In incorporating material by reference, the agency must designate in the rule whether or not the incorporation includes subsequent amendments and editions of the referenced material. The agency can change this designation only by a subsequent rule-making proceeding. The agency must have copies of the incorporated material available for inspection and must specify in the rule both where copies of the material can be obtained and the cost on the date the rule is adopted of a copy of the material.

A statement in a rule that a rule incorporates material by reference in accordance with former G.S. 150B-14(b) is a statement that the rule does not include subsequent amendments and editions of the referenced material. A statement in a rule that a rule incorporates material by reference in accordance with former G.S. 150B-14(c) is a statement that the rule includes subsequent amendments and editions of the referenced material.

**§ 150B-21.7. Effect of transfer of duties or termination of agency on rules.**

When a law that authorizes an agency to adopt a rule is repealed and another law gives the same or another agency substantially the same authority to adopt a rule, the rule remains in effect until the agency amends or repeals the rule. When a law that authorizes an agency to adopt a rule is repealed and another law does not give the same or



another agency substantially the same authority to adopt a rule, a rule adopted under the repealed law is repealed as of the date the law is repealed.

When an executive order abolishes part or all of an agency and transfers a function of that agency to another agency, a rule concerning the transferred function remains in effect until the agency to which the function is transferred amends or repeals the rule. When an executive order abolishes part or all of an agency and does not transfer a function of that agency to another agency, a rule concerning a function abolished by the executive order is repealed as of the effective date of the executive order.

The Director of Fiscal Research of the General Assembly must notify the Codifier of Rules when a rule is repealed under this section. When notified of a rule repealed under this section, the Codifier of Rules must enter the repeal of the rule in the North Carolina Administrative Code.

#### Part 3. Review by Commission.

#### § 150B-21.8. Review of rule by Commission.

(a) Temporary Rule. -- The Commission does not review a temporary rule.

(b) Permanent Rule. -- An agency must submit a permanent rule adopted by it to the Commission before the rule can be included in the North Carolina Administrative Code. The Commission reviews a permanent rule in accordance with the standards in G.S. 150B-21.9 and follows the procedure in this Part in its review of a permanent rule.

(c) Scope. -- When the Commission reviews an amendment to a rule, it may review the entire rule that is being amended. The procedure in G.S. 150B-21.12 applies when the Commission objects to a part of a rule that is within its scope of review but is not changed by a rule amendment.

#### § 150B-21.9. Standards and timetable for review by Commission.

(a) Standards. -- The Commission must determine whether a rule meets all of the following criteria:

- (1) It is within the authority delegated to the agency by the General Assembly.
- (2) It is clear and unambiguous.
- (3) It is reasonably necessary to fulfill a duty delegated to the agency by the General Assembly.

The Commission may determine if a rule submitted to it was adopted in accordance with Part 2 of this Article. The Commission must notify the agency that adopted the rule if it determines that a rule was not adopted in accordance with Part 2 of this Article and must return the rule to the agency.

Entry of a rule in the North Carolina Administrative Code after review by the Commission is conclusive evidence that the rule was adopted in accordance with Part 2 of this Article.

(b) Timetable. -- The Commission must review a rule submitted to it on or before the twentieth of a month by the last day of the next month. The Commission must review a rule submitted to it after the twentieth of a month by the last day of the second subsequent month.

#### § 150B-21.10. Commission action on permanent rule.

At the first meeting at which a permanent rule is before the Commission for review, the Commission must take one of the following actions:

- (1) Approve the rule, if the Commission determines that the rule meets the standards for review.
- (2) Object to the rule, if the Commission determines that the rule does not meet the standards for review.
- (3) Extend the period for reviewing the rule, if the Commission determines it needs additional information on the rule to be able to decide whether the rule meets the standards for review.

In reviewing a new rule or an amendment to an existing rule, the Commission may request an agency to make technical changes to the rule and may condition its approval of the rule on the agency's making the requested technical changes.

#### § 150B-21.11. Procedure when Commission approves permanent rule.

When the Commission approves a permanent rule, it must notify the agency that adopted the rule of the Commission's approval and must deliver the approved rule to the Codifier of Rules. The Commission must deliver an approved rule by the end of the month in which the Commission approved the rule, unless the agency asks the Commission to delay the delivery of the rule.

#### § 150B-21.12. Procedure when Commission objects to a permanent rule.

(a) Action. -- When the Commission objects to a permanent rule, it must send the agency that adopted the rule a written statement of the objection and the reason for the objection. The agency that adopted the rule must take one of the following actions:

- (1) Change the rule to satisfy the Commission's objection and submit the revised rule to the Commission.
- (2) Submit a written response to the Commission indicating that the agency has decided not to change the rule.

An agency that is not a board or commission must take one of these actions within 30 days after receiving the Commission's statement of objection. A board or commission must take one of these actions within 30 days after receiving the Commission's statement of objection or within 10 days after the board or commission's next regularly scheduled meeting, whichever comes later.

When an agency changes a rule in response to an objection by the Commission, the Commission must determine whether the change satisfies the Commission's objection. If it does, the Commission must approve the rule. If it does not, the Commission must send the agency a written statement of the Commission's continued objection and the reason for the continued objection.

A rule to which the Commission has objected remains under review by the Commission until the agency that adopted the rule decides not to satisfy the Commission's objection and makes a written request to the Commission to return the rule to the agency. When the Commission returns a rule to which it has objected, it may send to the President of the Senate and each member of the General Assembly a report of its objection to the rule.

(b) **Entry in Code.** -- When the Commission returns a rule to which it has objected to the agency that adopted the rule, the Commission must notify the Codifier of Rules of its action and of the basis of the Commission's objection. An agency whose rule is returned may file the rule with the Codifier of Rules. When the Codifier of Rules enters in the North Carolina Administrative Code a rule to which the Commission objected, the entry must reflect the Commission's objection and must state the standard on which the Commission based its objection.

**§ 150B-21.13. Procedure when Commission extends period for review of permanent rule.**

When the Commission extends the period for review of a permanent rule, it must notify the agency that adopted the rule of the extension and the reason for the extension. After the Commission extends the period for review of a rule, it may call a public hearing on the rule. Within 70 days after extending the period for review of a rule, the Commission must decide whether to approve the rule, object to the rule, or call a public hearing on the rule.

**§ 150B-21.14. Public hearing on a rule.**

The Commission may call a public hearing on a rule when it extends the period for review of the rule. At the request of an agency, the Commission may call a public hearing on a rule that is not before it for review. Calling a public hearing on

a rule not already before the Commission for review places the rule before the Commission for review. When the Commission decides to call a public hearing on a rule, it must publish notice of the public hearing in the North Carolina Register.

After a public hearing on a rule, the Commission must approve the rule or object to the rule in accordance with the standards and procedures in this Part. The Commission must make its decision of whether to approve or object to the rule within 70 days after the public hearing.

**§ 150B-21.15. Declaratory judgment action authorized when Commission objects to a permanent rule.**

(a) **Standing.** -- A person aggrieved by a permanent rule entered in the North Carolina Administrative Code with an objection by the Commission based on a lack of statutory authority may file an action for declaratory judgment in Wake County Superior Court pursuant to Article 26 of Chapter 1 of the General Statutes. In the action, the court shall determine whether the agency exceeded its authority in adopting the rule.

A declaratory judgment action under this section must be filed within 90 days after the rule that is the subject of the action is entered in the Code. Filing a petition for rule making or a request for a declaratory ruling with the agency that adopted the rule is not a prerequisite to filing an action under this section. A person who files an action for declaratory judgment under this section must serve a copy of the complaint on the agency that adopted the rule being contested, the Codifier of Rules, and the Commission.

(b) **Record.** -- Within 10 days after a declaratory judgment action is filed under this section, the agency that adopted the rule that is the subject of the action must send to the court the original or a certified copy of the record in the Commission's review of the rule. The record consists of the rule, the Commission's letter of objection to the rule, the agency's written response to the Commission's letter, and any other relevant documents before the Commission when it decided to object to the rule.

(c) **Effect.** -- A rule remains in effect during the pendency of an action for declaratory judgment under this section unless the court suspends the rule after finding that the agency that adopted the rule has no substantial likelihood of prevailing in the action.

(d) **Changes.** -- While a rule is the subject of a declaratory judgment action under this section, the agency that adopted the rule may submit to the Commission changes in the rule to satisfy the

Commission's objection. If the Commission determines that changes submitted to it satisfy its objection, the Commission must accept the changes and file the revised rule with the Codifier of Rules. The Codifier must then enter the rule in the North Carolina Administrative Code. When the Commission determines that changes submitted to it satisfy its objection, the agency that submitted the changes must notify the court of the changes and of the Commission's action.

Part 4. Publication of Code and Register.

**§ 150B-21.17. North Carolina Register.**

(a) Content. -- The Codifier of Rules must publish the North Carolina Register. The North Carolina Register must be published at least two times a month and must contain the following:

- (1) Notices of proposed adoptions of rules.
- (2) Notices of receipt of a petition for municipal incorporation, as required by G.S. 120-165.
- (3) Executive orders of the Governor.
- (4) Final decision letters from the United States Attorney General concerning changes in laws that affect voting in a jurisdiction subject to § 5 of the Voting Rights Act of 1965, as required by G.S. 120-30.9H.
- (5) Orders of the Tax Review Board issued under G.S. 105-241.2.
- (6) Other information the Codifier determines helpful to the public.

(b) Form. -- When an agency publishes notice in the North Carolina Register of the proposed text of a new rule, the Codifier of Rules must publish the complete text of the proposed new rule. In publishing the text of a proposed new rule, the Codifier must indicate the rule is new by underlining the proposed text of the rule.

When an agency publishes notice in the North Carolina Register of the proposed text of an amendment to an existing rule, the Codifier must publish the complete text of the rule that is being amended unless the Codifier determines that publication of the complete text of the rule being amended is not necessary to enable the reader to understand the proposed amendment. In publishing the text of a proposed amendment to a rule, the Codifier must indicate deleted text with overstrikes and added text with underlines.

When an agency publishes notice in the North Carolina Register of the proposed repeal of an existing rule, the Codifier must publish the complete text of the rule the agency proposes to repeal unless the Codifier determines that publication of the complete text is impractical. In publishing the

text of a rule the agency proposes to repeal, the Codifier must indicate the rule is to be repealed.

**§ 150B-21.18. North Carolina Administrative Code.**

The Codifier of Rules must compile all rules into a Code known as the North Carolina Administrative Code. The format and indexing of the Code must conform as nearly as practical to the format and indexing of the North Carolina General Statutes. The Codifier must publish printed copies of the Code and may publish the Code in other forms. The Codifier must keep the Code current by publishing the Code in a loose-leaf format and periodically providing new pages to be substituted for outdated pages, by publishing the Code in volumes and periodically publishing cumulative supplements, or by another means. The Codifier must keep superseded rules.

**§ 150B-21.19. Requirements for including rule in Code.**

To be acceptable for inclusion in the North Carolina Administrative Code, a rule must:

- (1) Cite the law under which the rule is adopted.
- (2) Be signed by the head of the agency or the rule-making coordinator for the agency that adopted the rule.
- (3) Be in the physical form specified by the Codifier of Rules.
- (4) Have been reviewed by the Commission, if the rule is a permanent rule.

**§ 150B-21.20. Codifier's authority to revise form of rules.**

(a) Authority. -- After consulting with the agency that adopted the rule, the Codifier of Rules may revise the form of a rule submitted for inclusion in the North Carolina Administrative Code within 10 business days after the rule is submitted to do one or more of the following:

- (1) Rearrange the order of the rule in the Code or the order of the subsections, subdivisions, or other subparts of the rule.
- (2) Provide a catch line or heading for the rule or revise the catch line or heading of the rule.
- (3) Reletter or renumber the rule or the subparts of the rule in accordance with a uniform system.
- (4) Rearrange definitions and lists.
- (5) Make other changes in arrangement or in form that do not change the substance of the rule and are necessary or desirable for a clear and orderly arrangement of the rule.

(b) Effect. -- Revision of a rule by the Codifier of Rules under this section does not affect the effective date of the rule or require the agency to readopt or resubmit the rule. When the Codifier of Rules revises the form of a rule, the Codifier of Rules must send the agency that adopted the rule a copy of the revised rule. The revised rule is the official rule.

**§ 150B-21.21. Publication of rules of North Carolina State Bar and exempt agencies.**

(a) State Bar. -- The North Carolina State Bar must submit a rule adopted or approved by it and entered in the minutes of the North Carolina Supreme Court to the Codifier of Rules for inclusion in the North Carolina Administrative Code. The State Bar must submit a rule within 15 days after it is entered in the minutes of the Supreme Court. The Codifier of Rules must compile, make available for public inspection, and publish a rule included in the North Carolina Administrative Code under this subsection in the same manner as other rules in the Code.

(b) Exempt Agencies. -- Notwithstanding G.S. 150B-1, the North Carolina Utilities Commission must submit to the Codifier of Rules those rules of the Utilities Commission that are published from time to time in the publication titled "North Carolina Utilities Laws and Regulations." The Utilities Commission must submit a rule required to be included in the Code within 15 days after it is adopted. The Codifier of Rules must publish the rules submitted by the Utilities Commission in the North Carolina Administrative Code in the same format as they are submitted.

Notwithstanding G.S. 150B-1, an agency other than the Utilities Commission that is exempted from this Article by that statute must submit a temporary or permanent rule adopted by it to the Codifier of Rules for inclusion in the North Carolina Administrative Code. One of these exempt agencies must submit a rule to the Codifier of Rules within 15 days after it adopts the rule. The Codifier of Rules must compile, make available for public inspection, and publish a rule of one of these agencies in the North Carolina Administrative Code in the same manner as other rules in the Code.

**§ 150B-21.22. Effect of inclusion in Code.**

Official or judicial notice can be taken of a rule in the North Carolina Administrative Code and shall be taken when appropriate. Codification of a rule in the North Carolina Administrative Code is *prima facie* evidence of compliance with this Article.

**§ 150B-21.23. Rule publication manual.**

The Codifier of Rules must publish a manual that sets out the form and method for publishing a notice of rule making in the North Carolina Register and for filing a rule in the North Carolina Administrative Code.

**§ 150B-21.24. Free copies of Register and Code.**

(a) Register. -- The Codifier of Rules must distribute copies of the North Carolina Register as soon after publication as practical, without charge, to the following:

- (1) A person who receives a free copy of the North Carolina Administrative Code.
- (2) Upon request, one copy to each member of the General Assembly.

(b) Code. -- The Codifier of Rules must distribute copies of the North Carolina Administrative Code as soon after publication as practical, without charge, to the following:

- (1) One copy to the board of commissioners of each county, to be placed at the county clerk of court's office or at another place selected by the board of commissioners.
- (2) One copy to the Commission.
- (3) One copy to the Clerk of the Supreme Court and to the Clerk of the Court of Appeals of North Carolina.
- (4) One copy to the Supreme Court Library and one copy to the library of the Court of Appeals.
- (5) One copy to the Administrative Office of the Courts.
- (6) One copy to the Governor.
- (7) Five copies to the Legislative Services Commission for the use of the General Assembly.
- (8) Upon request, one copy to each State official or department to whom or to which copies of the appellate division reports are furnished under G.S. 7A-343.1.
- (9) Five copies to the Division of State Library of the Department of Cultural Resources pursuant to G.S. 125-11.7.

**§ 150B-21.25. Paid copies of Register and Code.**

A person who is not entitled to a free copy of the North Carolina Administrative Code or North Carolina Register may obtain a copy by paying a fee set by the Codifier of Rules. The Codifier must set separate fees for the North Carolina Register and the North Carolina Administrative Code in amounts that cover publication, copying,

and mailing costs. All monies received under this section must be credited to the General Fund.

Article 3.

Administrative Hearings.

§ 150B-22. Settlement; contested case.

It is the policy of this State that any dispute between an agency and another person that involves the person's rights, duties, or privileges, including licensing or the levy of a monetary penalty, should be settled through informal procedures. In trying to reach a settlement through informal procedures, the agency may not conduct a proceeding at which sworn testimony is taken and witnesses may be cross-examined. If the agency and the other person do not agree to a resolution of the dispute through informal procedures, either the agency or the person may commence an administrative proceeding to determine the person's rights, duties, or privileges, at which time the dispute becomes a "contested case."

§ 150B-23. Commencement; assignment of administrative law judge; hearing required; notice; intervention.

(a) A contested case shall be commenced by filing a petition with the Office of Administrative Hearings and, except as provided in Article 3A of this Chapter, shall be conducted by that Office. The party who files the petition shall serve a copy of the petition on all other parties and, if the dispute concerns a license, the person who holds the license. A party who files a petition shall file a certificate of service together with the petition. A petition shall be signed by a party or a representative of the party and, if filed by a party other than an agency, shall state facts tending to establish that the agency named as the respondent has deprived the petitioner of property, has ordered the petitioner to pay a fine or civil penalty, or has otherwise substantially prejudiced the petitioner's rights and that the agency:

- (1) Exceeded its authority or jurisdiction;
- (2) Acted erroneously;
- (3) Failed to use proper procedure;
- (4) Acted arbitrarily or capriciously; or
- (5) Failed to act as required by law or rule.

The parties in a contested case shall be given an opportunity for a hearing without undue delay. Any person aggrieved may commence a contested case hereunder.

A local government employee, applicant for employment, or former employee to whom Chapter 126 of the General Statutes applies may commence a contested case under this Article in the same manner as any other petitioner. The case shall be conducted in the Office of Administrative

Hearings in the same manner as other contested cases under this Article, except that the decision of the State Personnel Commission shall be advisory only and not binding on the local appointing authority, unless (1) the employee, applicant, or former employee has been subjected to discrimination prohibited by Article 6 of Chapter 126 of the General Statutes or (2) applicable federal standards require a binding decision. In these two cases, the State Personnel Commission's decision shall be binding.

(a1) Repealed by Session Laws 1985 (Reg. Sess., 1986), c. 1022, s. 1(9).

(a2) An administrative law judge assigned to a contested case may require a party to the case to file a prehearing statement. A party's prehearing statement must be served on all other parties to the contested case.

(b) The parties to a contested case shall be given a notice of hearing not less than 15 days before the hearing by the Office of Administrative Hearings. If prehearing statements have been filed in the case, the notice shall state the date, hour, and place of the hearing. If prehearing statements have not been filed in the case, the notice shall state the date, hour, place, and nature of the hearing, shall list the particular sections of the statutes and rules involved, and shall give a short and plain statement of the factual allegations.

(c) Notice shall be given personally or by certified mail. If given by certified mail, it shall be deemed to have been given on the delivery date appearing on the return receipt. If giving of notice cannot be accomplished either personally or by certified mail, notice shall then be given in the manner provided in G.S. 1A-1, Rule 4(j1).

(d) Any person may petition to become a party by filing a motion to intervene in the manner provided in G.S. 1A-1, Rule 24. In addition, any person interested in a contested case may intervene and participate in that proceeding to the extent deemed appropriate by the administrative law judge.

(e) All hearings under this Chapter shall be open to the public. Hearings shall be conducted in an impartial manner. Hearings shall be conducted according to the procedures set out in this Article, except to the extent and in the particulars that specific hearing procedures and time standards are governed by another statute.

(f) Unless another statute or a federal statute or regulation sets a time limitation for the filing of a petition in contested cases against a specified agency, the general limitation for the filing of a petition in a contested case is 60 days. The time

limitation, whether established by another statute, federal statute, or federal regulation, or this section, shall commence when notice is given of the agency decision to all persons aggrieved who are known to the agency by personal delivery or by the placing of the notice in an official depository of the United States Postal Service wrapped in a wrapper addressed to the person at the latest address given by the person to the agency. The notice shall be in writing, and shall set forth the agency action, and shall inform the persons of the right, the procedure, and the time limit to file a contested case petition. When no informal settlement request has been received by the agency prior to issuance of the notice, any subsequent informal settlement request shall not suspend the time limitation for the filing of a petition for a contested case hearing.

**§ 150B-24. Venue of hearing.**

(a) The hearing of a contested case shall be conducted:

- (1) In the county in this State in which any person whose property or rights are the subject matter of the hearing maintains his residence;
- (2) In the county where the agency maintains its principal office if the property or rights that are the subject matter of the hearing do not affect any person or if the subject matter of the hearing is the property or rights of residents of more than one county; or
- (3) In any county determined by the administrative law judge in his discretion to promote the ends of justice or better serve the convenience of witnesses.

(b) Any person whose property or rights are the subject matter of the hearing waives his objection to venue by proceeding in the hearing.

**§ 150B-25. Conduct of hearing; answer.**

(a) If a party fails to appear in a contested case after proper service of notice, and if no adjournment or continuance is granted, the administrative law judge may proceed with the hearing in the absence of the party.

(b) Repealed.

(c) The parties shall be given an opportunity to present arguments on issues of law and policy and an opportunity to present evidence on issues of fact.

(d) A party may cross-examine any witness, including the author of a document prepared by, on behalf of, or for use of the agency and offered in evidence. Any party may submit rebuttal evidence.

**§ 150B-26. Consolidation.**

When contested cases involving a common question of law or fact or multiple proceedings involving the same or related parties are pending, the Director of the Office of Administrative Hearings may order a joint hearing of any matters at issue in the cases, order the cases consolidated, or make other orders to reduce costs or delay in the proceedings.

**§ 150B-27. Subpoena.**

After the commencement of a contested case, subpoenas may be issued and served in accordance with G.S. 1A-1, Rule 45. In addition to the methods of service in G.S. 1A-1, Rule 45, a State law enforcement officer may serve a subpoena on behalf of an agency that is a party to the contested case by any method by which a sheriff may serve a subpoena under that Rule. Upon a motion, the administrative law judge may quash a subpoena if, upon a hearing, the administrative law judge finds that the evidence the production of which is required does not relate to a matter in issue, the subpoena does not describe with sufficient particularity the evidence the production of which is required, or for any other reason sufficient in law the subpoena may be quashed. Witness fees shall be paid by the party requesting the subpoena to subpoenaed witnesses in accordance with G.S. 7A-314. However, State officials or employees who are subpoenaed shall not be entitled to witness fees, but they shall receive their normal salary and they shall not be required to take any annual leave for the witness days. Travel expenses of State officials or employees who are subpoenaed shall be reimbursed as provided in G.S. 138-6.

**§ 150B-28. Depositions and discovery.**

(a) A deposition may be used in lieu of other evidence when taken in compliance with the Rules of Civil Procedure, G.S. 1A-1. Parties in contested cases may engage in discovery pursuant to the provisions of the Rules of Civil Procedure, G.S. 1A-1.

(b) On a request for identifiable agency records, with respect to material facts involved in a contested case, except records related solely to the internal procedures of the agency or which are exempt from disclosure by law, an agency shall promptly make the records available to a party.

**§ 150B-29. Rules of evidence.**

(a) In all contested cases, irrelevant, immaterial and unduly repetitious evidence shall be excluded. Except as otherwise provided, the rules of evidence as applied in the trial division of the General Court of Justice shall be followed; but, when evidence is not reasonably available under the rules to show relevant facts, then the most reliable

and substantial evidence available shall be admitted. On the judge's own motion, an administrative law judge may exclude evidence that is inadmissible under this section. It shall not be necessary for a party or his attorney to object at the hearing to evidence in order to preserve the right to object to its consideration by the administrative law judge in making a recommended decision, by the agency in making a final decision, or by the court on judicial review.

(b) Evidence in a contested case, including records and documents, shall be offered and made a part of the record. Factual information or evidence not made a part of the record shall not be considered in the determination of the case, except as permitted under G.S. 150B-30. Documentary evidence may be received in the form of a copy or excerpt or may be incorporated by reference, if the materials so incorporated are available for examination by the parties. Upon timely request, a party shall be given an opportunity to compare the copy with the original if available.

#### **§ 150B-30. Official notice.**

Official notice may be taken of all facts of which judicial notice may be taken and of other facts within the specialized knowledge of the agency. The noticed fact and its source shall be stated and made known to affected parties at the earliest practicable time, and any party shall on timely request be afforded an opportunity to dispute the noticed fact through submission of evidence and argument.

#### **§ 150B-31. Stipulations.**

(a) The parties in a contested case may, by a stipulation in writing filed with the administrative law judge, agree upon any fact involved in the controversy, which stipulation shall be used as evidence at the hearing and be binding on the parties thereto. Parties should agree upon facts when practicable.

(b) Except as otherwise provided by law, disposition may be made of a contested case by stipulation, agreed settlement, consent order, waiver, default, or other method agreed upon by the parties.

#### **§ 150B-32. Designation of administrative law judge.**

(a) The Director of the Office of Administrative Hearings shall assign himself or another administrative law judge to preside over a contested case.

(a1) Repealed by Session Laws 1985 (Reg. Sess., 1986), c. 1022, s. 1 (15), effective July 15, 1986.

(b) On the filing in good faith by a party of a timely and sufficient affidavit of personal bias or

disqualification of an administrative law judge, the administrative law judge shall determine the matter as a part of the record in the case, and this determination shall be subject to judicial review at the conclusion of the proceeding.

(c) When an administrative law judge is disqualified or it is impracticable for him to continue the hearing, the Director shall assign another administrative law judge to continue with the case unless it is shown that substantial prejudice to any party will result, in which event a new hearing shall be held or the case dismissed without prejudice.

#### **§ 150B-33. Powers of administrative law judge.**

(a) An administrative law judge shall stay any contested case under this Article on motion of an agency which is a party to the contested case, if the agency shows by supporting affidavits that it is engaged in other litigation or administrative proceedings, by whatever name called, with or before a federal agency, and this other litigation or administrative proceedings will determine the position, in whole or in part, of the agency in the contested case. At the conclusion of the other litigation or administrative proceedings, the contested case shall proceed and be determined as expeditiously as possible.

(b) An administrative law judge may:

- (1) Administer oaths and affirmations;
- (2) Sign, issue, and rule on subpoenas in accordance with G.S. 150B-27 and G.S. 1A-1, Rule 45;
- (3) Provide for the taking of testimony by deposition and rule on all objections to discovery in accordance with G.S. 1A-1, the Rules of Civil Procedure;
- (3a) Rule on all prehearing motions that are authorized by G.S. 1A-1, the Rules of Civil Procedure;
- (4) Regulate the course of the hearings, including discovery, set the time and place for continued hearings, and fix the time for filing of briefs and other documents;
- (5) Direct the parties to appear and confer to consider simplification of the issues by consent of the parties;
- (6) Stay the contested action by the agency pending the outcome of the case, upon such terms as he deems proper, and subject to the provisions of G.S. 1A-1, Rule 65;
- (7) Determine whether the hearing shall be recorded by a stenographer or by an electronic device; and



- (8) Enter an order returnable in the General Court of Justice, Superior Court Division, to show cause why the person should not be held in contempt. The Court shall have the power to impose punishment as for contempt for any act which would constitute direct or indirect contempt if the act occurred in an action pending in Superior Court.
- (9) Determine that a rule as applied in a particular case is void because (1) it is not within the statutory authority of the agency, (2) is not clear and unambiguous to persons it is intended to direct, guide, or assist, or (3) is not reasonably necessary to enable the agency to fulfill a duty delegated to it by the General Assembly.
- (10) Impose the sanctions provided for in G.S. 1A-1 or Chapter 3 of Title 26 of the North Carolina Administrative Code for noncompliance with applicable procedural rules.

**§ 150B-34. Recommended decision or order of administrative law judge.**

(a) Except as provided in G.S. 150B-36(c), in each contested case the administrative law judge shall make a recommended decision or order that contains findings of fact and conclusions of law.

(b) Repealed.

**§ 150B-35. No ex parte communication; exceptions.**

Unless required for disposition of an ex parte matter authorized by law, neither the administrative law judge assigned to a contested case nor a member or employee of the agency making a final decision in the case may communicate, directly or indirectly, in connection with any issue of fact, or question of law, with any person or party or his representative, except on notice and opportunity for all parties to participate.

**§ 150B-36. Final decision.**

(a) Before the agency makes a final decision, it shall give each party an opportunity to file exceptions to the decision recommended by the administrative law judge, and to present written arguments to those in the agency who will make the final decision or order. If a party files in good faith a timely and sufficient affidavit of personal bias or other reason for disqualification of a member of the agency making the final decision, the agency shall determine the matter as a part of the record in the case, and the determination is subject to judicial review at the conclusion of the case.

(b) A final decision or order in a contested case

shall be made by the agency in writing after review of the official record as defined in G.S. 150B-37(a) and shall include findings of fact and conclusions of law. If the agency does not adopt the administrative law judge's recommended decision as its final decision, the agency shall state in its decision or order the specific reasons why it did not adopt the administrative law judge's recommended decision. The agency may consider only the official record prepared pursuant to G.S. 150B-37 in making a final decision or order, and the final decision or order shall be supported by substantial evidence admissible under G.S. 150B-29(a), 150B-30, or 150B-31. A copy of the decision or order shall be served upon each party personally or by certified mail addressed to the party at the latest address given by the party to the agency, and a copy shall be furnished to his attorney of record and the Office of Administrative Hearings.

(c) The following decisions made by administrative law judges in contested cases are final decisions:

- (1) A determination that the Office of Administrative Hearings lacks jurisdiction.
- (2) An order entered pursuant to the authority in G.S. 7A-759(e).
- (3) An order entered pursuant to a written prehearing motion that either dismisses the contested case for failure of the petitioner to prosecute or grants the relief requested when a party does not comply with procedural requirements.
- (4) An order entered pursuant to a prehearing motion to dismiss the contested case in accordance with G.S. 1A-1, Rule 12(b) when the order disposes of all issues in the contested case.

**§ 150B-37. Official record.**

(a) In a contested case, the Office of Administrative Hearings shall prepare an official record of the case that includes:

- (1) Notices, pleadings, motions, and intermediate rulings;
- (2) Questions and offers of proof, objections, and rulings thereon;
- (3) Evidence presented;
- (4) Matters officially noticed, except matters so obvious that a statement of them would serve no useful purpose; and
- (5) Repealed by Session Laws 1987, c. 878, s. 25, effective August 14, 1987.
- (6) The administrative law judge's recommended decision or order.



(b) Proceedings at which oral evidence is presented shall be recorded, but need not be transcribed unless requested by a party. Each party shall bear the cost of the transcript or part thereof or copy of said transcript or part thereof which said party requests, and said transcript or part thereof shall be added to the official record as an exhibit.

(c) The Office of Administrative Hearings shall forward a copy of the official record to the agency making the final decision and shall forward a copy of the recommended decision to each party.

#### Article 3A.

#### Other Administrative Hearings.

### § 150B-38. Scope; hearing required; notice; venue.

(a) The provisions of this Article shall apply to the following agencies:

- (1) Occupational licensing agencies;
- (2) The State Banking Commission, the Commissioner of Banks, the Savings Institutions Division of the Department of ~~Economic and Community Development~~, Commerce, and the Credit Union Division of the Department of ~~Economic and Community Development~~, Commerce; and
- (3) The Department of Insurance and the Commissioner of Insurance.

(b) Prior to any agency action in a contested case, the agency shall give the parties in the case an opportunity for a hearing without undue delay and notice not less than 15 days before the hearing. Notice to the parties shall include:

- (1) A statement of the date, hour, place, and nature of the hearing;
- (2) A reference to the particular sections of the statutes and rules involved; and
- (3) A short and plain statement of the facts alleged.

(c) Notice shall be given personally or by certified mail. If given by certified mail, notice shall be deemed to have been given on the delivery date appearing on the return receipt. If notice cannot be given personally or by certified mail, then notice shall be given in the manner provided in G.S. 1A-1, Rule 4(j1).

(d) A party who has been served with a notice of hearing may file a written response with the agency. If a written response is filed, a copy of the response must be mailed to all other parties not less than 10 days before the date set for the hearing.

(e) All hearings conducted under this Article shall be open to the public. A hearing conducted

by the agency shall be held in the county where the agency maintains its principal office. A hearing conducted for the agency by an administrative law judge requested under G.S. 150B-40 shall be held in a county in this State where any person whose property or rights are the subject matter of the hearing resides. If a different venue would promote the ends of justice or better serve the convenience of witnesses, the agency or the administrative law judge may designate another county. A person whose property or rights are the subject matter of the hearing waives his objection to venue if he proceeds in the hearing.

(f) Any person may petition to become a party by filing with the agency or hearing officer a motion to intervene in the manner provided by G.S. 1A-1, Rule 24. In addition, any person interested in a contested case under this Article may intervene and participate to the extent deemed appropriate by the agency hearing officer.

(g) When contested cases involving a common question of law or fact or multiple proceedings involving the same or related parties are pending before an agency, the agency may order a joint hearing of any matters at issue in the cases, order the cases consolidated, or make other orders to reduce costs or delay in the proceedings.

(h) Every agency shall adopt rules governing the conduct of hearings that are consistent with the provisions of this Article.

### § 150B-39. Depositions; discovery; subpoenas.

(a) A deposition may be used in lieu of other evidence when taken in compliance with the Rules of Civil Procedure, G.S. 1A-1. Parties in a contested case may engage in discovery pursuant to the provisions of the Rules of Civil Procedure, G.S. 1A-1.

(b) Upon a request for an identifiable agency record involving a material fact in a contested case, the agency shall promptly provide the record to a party, unless the record relates solely to the agency's internal procedures or is exempt from disclosure by law.

(c) In preparation for, or in the conduct of, a contested case subpoenas may be issued and served in accordance with G.S. 1A-1, Rule 45. Upon a motion, the agency may quash a subpoena if, upon a hearing, the agency finds that the evidence, the production of which is required, does not relate to a matter in issue, the subpoena does not describe with sufficient particularity the evidence the production of which is required, or for any other reason sufficient in law the subpoena may be quashed. Witness fees shall be paid by the party

requesting the subpoena to subpoenaed witnesses in accordance with G.S. 7A-314. However, State officials or employees who are subpoenaed shall not be entitled to any witness fees, but they shall receive their normal salary and they shall not be required to take any annual leave for the witness days. Travel expenses of State officials or employees who are subpoenaed shall be reimbursed as provided in G.S. 138-6.

**§ 150B-40. Conduct of hearing; presiding officer; ex parte communication.**

(a) Hearings shall be conducted in a fair and impartial manner. At the hearing, the agency and the parties shall be given an opportunity to present evidence on issues of fact, examine and cross-examine witnesses, including the author of a document prepared by, on behalf of or for the use of the agency and offered into evidence, submit rebuttal evidence, and present arguments on issues of law or policy.

If a party fails to appear in a contested case after he has been given proper notice, the agency may continue the hearing or proceed with the hearing and make its decision in the absence of the party.

(b) Except as provided under subsection (e) of this section, hearings under this Article shall be conducted by a majority of the agency. An agency shall designate one or more of its members to preside at the hearing. If a party files in good faith a timely and sufficient affidavit of the personal bias or other reason for disqualification of any member of the agency, the agency shall determine the matter as a part of the record in the case, and its determination shall be subject to judicial review at the conclusion of the proceeding. If a presiding officer is disqualified or it is impracticable for him to continue the hearing, another presiding officer shall be assigned to continue with the case, except that if assignment of a new presiding officer will cause substantial prejudice to any party, a new hearing shall be held or the case dismissed without prejudice.

(c) The presiding officer may:

- (1) Administer oaths and affirmations;
- (2) Sign and issue subpoenas in the name of the agency, requiring attendance and giving of testimony by witnesses and the production of books, papers, and other documentary evidence;
- (3) Provide for the taking of testimony by deposition;
- (4) Regulate the course of the hearings, set the time and place for continued hearings, and fix the time for filing of briefs and other documents;

- (5) Direct the parties to appear and confer to consider simplification of the issues by consent of the parties; and
- (6) Apply to any judge of the superior court resident in the district or presiding at a term of court in the county where a hearing is pending for an order to show cause why any person should not be held in contempt of the agency and its processes, and the court shall have the power to impose punishment as for contempt for acts which would constitute direct or indirect contempt if the acts occurred in an action pending in superior court.

(d) Unless required for disposition of an ex parte matter authorized by law, a member of an agency assigned to make a decision or to make findings of fact and conclusions of law in a contested case under this Article shall not communicate, directly or indirectly, in connection with any issue of fact or question of law, with any person or party or his representative, except on notice and opportunity for all parties to participate. This prohibition begins at the time of the notice of hearing. An agency member may communicate with other members of the agency and may have the aid and advice of the agency staff other than the staff which has been or is engaged in investigating or prosecuting functions in connection with the case under consideration or a factually-related case. This section does not apply to an agency employee or party representative with professional training in accounting, actuarial science, economics or financial analysis insofar as the case involves financial practices or conditions.

(e) When a majority of an agency is unable or elects not to hear a contested case, the agency shall apply to the Director of the Office of Administrative Hearings for the designation of an administrative law judge to preside at the hearing of a contested case under this Article. Upon receipt of the application, the Director shall, without undue delay, assign an administrative law judge to hear the case.

The provisions of this Article, rather than the provisions of Article 3, shall govern a contested case in which the agency requests an administrative law judge from the Office of Administrative Hearings.

The administrative law judge assigned to hear a contested case under this Article shall sit in place of the agency and shall have the authority of the presiding officer in a contested case under this Article. The administrative law judge shall make

a proposal for decision, which shall contain proposed findings of fact and proposed conclusions of law.

An administrative law judge shall stay any contested case under this Article on motion of an agency which is a party to the contested case, if the agency shows by supporting affidavits that it is engaged in other litigation or administrative proceedings, by whatever name called, with or before a federal agency, and this other litigation or administrative proceedings will determine the position, in whole or in part, of the agency in the contested case. At the conclusion of the other litigation or administrative proceedings, the contested case shall proceed and be determined as expeditiously as possible.

The agency may make its final decision only after the administrative law judge's proposal for decision is served on the parties, and an opportunity is given to each party to file exceptions and proposed findings of fact and to present oral and written arguments to the agency.

**§ 150B-41. Evidence; stipulations; official notice.**

(a) In all contested cases, irrelevant, immaterial, and unduly repetitious evidence shall be excluded. Except as otherwise provided, the rules of evidence as applied in the trial division of the General Court of Justice shall be followed; but, when evidence is not reasonably available under such rules to show relevant facts, they may be shown by the most reliable and substantial evidence available. It shall not be necessary for a party or his attorney to object to evidence at the hearing in order to preserve the right to object to its consideration by the agency in reaching its decision, or by the court of judicial review.

(b) Evidence in a contested case, including records and documents shall be offered and made a part of the record. Other factual information or evidence shall not be considered in determination of the case, except as permitted under G.S. 150B-30. Documentary evidence may be received in the form of a copy or excerpt or may be incorporated by reference, if the materials so incorporated are available for examination by the parties. Upon timely request, a party shall be given an opportunity to compare the copy with the original if available.

(c) The parties in a contested case under this Article by a stipulation in writing filed with the agency may agree upon any fact involved in the controversy, which stipulation shall be used as evidence at the hearing and be binding on the parties thereto. Parties should agree upon facts

when practicable. Except as otherwise provided by law, disposition may be made of a contested case by stipulation, agreed settlement, consent order, waiver, default, or other method agreed upon by the parties.

(d) Official notice may be taken of all facts of which judicial notice may be taken and of other facts within the specialized knowledge of the agency. The noticed fact and its source shall be stated and made known to affected parties at the earliest practicable time, and any party shall on timely request be afforded an opportunity to dispute the noticed fact through submission of evidence and argument. An agency may use its experience, technical competence, and specialized knowledge in the evaluation of evidence presented to it.

**§ 150B-42. Final agency decision; official record.**

(a) After compliance with the provisions of G.S. 150B-40(e), if applicable, and review of the official record, as defined in subsection (b) of this section, an agency shall make a written final decision or order in a contested case. The decision or order shall include findings of fact and conclusions of law. Findings of fact shall be based exclusively on the evidence and on matters officially noticed. Findings of fact, if set forth in statutory language, shall be accompanied by a concise and explicit statement of the underlying facts supporting them. A decision or order shall not be made except upon consideration of the record as a whole or such portion thereof as may be cited by any party to the proceeding and shall be supported by substantial evidence admissible under G.S. 150B-41. A copy of the decision or order shall be served upon each party personally or by certified mail addressed to the party at the latest address given by the party to the agency and a copy shall be furnished to his attorney of record.

(b) An agency shall prepare an official record of a hearing that shall include:

- (1) Notices, pleadings, motions, and intermediate rulings;
- (2) Questions and offers of proof, objections, and rulings thereon;
- (3) Evidence presented;
- (4) Matters officially noticed, except matters so obvious that a statement of them would serve no useful purpose;
- (5) Proposed findings and exceptions; and
- (6) Any decision, opinion, order, or report by the officer presiding at the hearing and by the agency.

(c) Proceedings at which oral evidence is pre-

sented shall be recorded, but need not be transcribed unless requested by a party. Each party shall bear the cost of the transcript or part thereof or copy of said transcript or part thereof which said party requests.

#### Article 4.

##### Judicial Review.

#### § 150B-43. Right to judicial review.

Any person who is aggrieved by the final decision in a contested case, and who has exhausted all administrative remedies made available to him by statute or agency rule, is entitled to judicial review of the decision under this Article, unless adequate procedure for judicial review is provided by another statute, in which case the review shall be under such other statute. Nothing in this Chapter shall prevent any person from invoking any judicial remedy available to him under the law to test the validity of any administrative action not made reviewable under this Article.

#### § 150B-44. Right to judicial intervention when decision unreasonably delayed.

Unreasonable delay on the part of any agency or administrative law judge in taking any required action shall be justification for any person whose rights, duties, or privileges are adversely affected by such delay to seek a court order compelling action by the agency or administrative law judge. An agency that is subject to Article 3 of this Chapter and is not a board or commission has 90 days from the day it receives the official record in a contested case from the Office of Administrative Hearings to make a final decision in the case. This time limit may be extended by the parties or, for good cause shown, by the agency for an additional period of up to 90 days. An agency that is subject to Article 3 of this Chapter and is a board or commission has 90 days from the day it receives the official record in a contested case from the Office of Administrative Hearings or 90 days after its next regularly scheduled meeting, whichever is longer, to make a final decision in the case. This time limit may be extended by the parties or, for good cause shown, by the agency for an additional period of up to 90 days. If an agency subject to Article 3 of this Chapter has not made a final decision within these time limits, the agency is considered to have adopted the administrative law judge's recommended decision as the agency's final decision. Failure of an agency subject to Article 3A of this Chapter to make a final decision within 180 days of the close of the contested case hearing is justification for a person whose rights, duties, or privileges are adversely affected by the delay to seek a court order compel-

ling action by the agency or, if the case was heard by an administrative law judge, by the administrative law judge.

#### § 150B-45. Procedure for seeking review; waiver.

To obtain judicial review of a final decision under this Article, the person seeking review must file a petition in the Superior Court of Wake County or in the superior court of the county where the person resides.

The person seeking review must file the petition within 30 days after the person is served with a written copy of the decision. A person who fails to file a petition within the required time waives the right to judicial review under this Article. For good cause shown, however, the superior court may accept an untimely petition.

#### § 150B-46. Contents of petition; copies served on all parties; intervention.

The petition shall explicitly state what exceptions are taken to the decision or procedure and what relief the petitioner seeks. Within 10 days after the petition is filed with the court, the party seeking the review shall serve copies of the petition by personal service or by certified mail upon all who were parties of record to the administrative proceedings. Names and addresses of such parties shall be furnished to the petitioner by the agency upon request. Any party to the administrative proceeding is a party to the review proceedings unless the party withdraws by notifying the court of the withdrawal and serving the other parties with notice of the withdrawal. Other parties to the proceeding may file a response to the petition within 30 days of service. Parties, including agencies, may state exceptions to the decision or procedure and what relief is sought in the response.

Any person aggrieved may petition to become a party by filing a motion to intervene as provided in G.S. 1A-1, Rule 24.

#### § 150B-47. Records filed with clerk of superior court; contents of records; costs.

Within 30 days after receipt of the copy of the petition for review, or within such additional time as the court may allow, the agency that made the final decision in the contested case shall transmit to the reviewing court the original or a certified copy of the official record in the contested case under review together with: (i) any exceptions, proposed findings of fact, or written arguments submitted to the agency in accordance with G.S. 150B-36(a); and (ii) the agency's final decision or order. With the permission of the court, the record may be shortened by stipulation of all

parties to the review proceedings. Any party unreasonably refusing to stipulate to limit the record may be taxed by the court for such additional costs as may be occasioned by the refusal. The court may require or permit subsequent corrections or additions to the record when deemed desirable.

**§ 150B-48. Stay of decision.**

At any time before or during the review proceeding, the person aggrieved may apply to the reviewing court for an order staying the operation of the administrative decision pending the outcome of the review. The court may grant or deny the stay in its discretion upon such terms as it deems proper and subject to the provisions of G.S. 1A-1, Rule 65.

**§ 150B-49. New evidence.**

An aggrieved person who files a petition in the superior court may apply to the court to present additional evidence. If the court is satisfied that the evidence is material to the issues, is not merely cumulative, and could not reasonably have been presented at the administrative hearing, the court may remand the case so that additional evidence can be taken. If an administrative law judge did not make a recommended decision in the case, the court shall remand the case to the agency that conducted the administrative hearing. After hearing the evidence, the agency may affirm or modify its previous findings of fact and final decision. If an administrative law judge made a recommended decision in the case, the court shall remand the case to the administrative law judge. After hearing the evidence, the administrative law judge may affirm or modify his previous findings of fact and recommended decision. The administrative law judge shall forward a copy of his decision to the agency that made the final decision, which in turn may affirm or modify its previous findings of fact and final decision. The additional evidence and any affirmation or modification of a recommended decision or final decision shall be made part of the official record.

**§ 150B-50. Review by superior court without jury.**

The review by a superior court of agency decisions under this Chapter shall be conducted by the court without a jury.

**§ 150B-51. Scope of review.**

(a) Initial Determination in Certain Cases. In reviewing a final decision in a contested case in which an administrative law judge made a recommended decision, the court shall make two initial determinations. First, the court shall determine whether the agency heard new evidence after

receiving the recommended decision. If the court determines that the agency heard new evidence, the court shall reverse the decision or remand the case to the agency to enter a decision in accordance with the evidence in the official record. Second, if the agency did not adopt the recommended decision, the court shall determine whether the agency's decision states the specific reasons why the agency did not adopt the recommended decision. If the court determines that the agency did not state specific reasons why it did not adopt a recommended decision, the court shall reverse the decision or remand the case to the agency to enter the specific reasons.

(b) Standard of Review. After making the determinations, if any, required by subsection (a), the court reviewing a final decision may affirm the decision of the agency or remand the case for further proceedings. It may also reverse or modify the agency's decision if the substantial rights of the petitioners may have been prejudiced because the agency's findings, inferences, conclusions, or decisions are:

- (1) In violation of constitutional provisions;
- (2) In excess of the statutory authority or jurisdiction of the agency;
- (3) Made upon unlawful procedure;
- (4) Affected by other error of law;
- (5) Unsupported by substantial evidence admissible under G.S. 150B-29(a), 150B-30, or 150B-31 in view of the entire record as submitted; or
- (6) Arbitrary or capricious.

**§ 150B-52. Appeal; stay of court's decision.**

A party to a review proceeding in a superior court may appeal to the appellate division from the final judgment of the superior court as provided in G.S. 7A-27. Pending the outcome of an appeal, an appealing party may apply to the court that issued the judgment under appeal for a stay of that judgment or a stay of the administrative decision that is the subject of the appeal, as appropriate.

Article 5.

Publication of Administrative Rules.

Repealed.

EXECUTIVE ORDER NUMBER 183  
AMENDING AND REISSUING THE PROVISIONS  
OF EXECUTIVE ORDER NUMBER 175

Hurricane Andrew relief efforts necessitate another temporary period of exemption from weight restrictions on vehicles transporting supplies and equipment through North Carolina from the areas of disaster caused by Hurricane Andrew.

Pursuant to the authority vested in me as Governor of North Carolina under the constitution and laws of this State, **IT IS ORDERED:**

Executive Order Number 175 dated August 28, 1992 is reissued with the following amendments:

**Section 1.**

- (4) Upon entering North Carolina, the vehicles will stop at the first available vehicle weight station and produce identification sufficient to establish that its load was used for the Hurricane Andrew relief effort. All other safety restrictions apply. If returning vehicles are loaded with some other backhaul, all normal weight and permit restrictions apply.

**Section 2.**

The \$50.00 fee listed in N.C.G.S. 105 - 449.49 for a temporary trip permit is waived for the vehicles described above. The penalties described in N.C.G.S. 20 - 382 concerning insurance registration are waived also. Finally, no quarterly fuel tax is required because the exception in N.C.G.S. 105 - 449.45 (a)(1) applies.

**Section 3** is deleted.

This Order is effective December 16, 1992 and shall remain in effect until December 23, 1992.

Done in Raleigh, North Carolina, this the 7th day of December, 1992.

NORTH CAROLINA WILDLIFE RESOURCES COMMISSION

PROCLAMATION

Charles R. Fullwood, Executive Director, North Carolina Wildlife Resources Commission, acting pursuant to North Carolina General Statute §113-292 (cl) and authority duly delegated by the Wildlife Resources Commission, hereby declares that the season for harvesting striped bass by hook-and-line shall remain closed in all waters of the Roanoke River Striped Bass Management Area until 12:00 p.m. 28 February 1993.

The Roanoke River Striped Bass Management Area is defined as the inland and joint fishing waters of the Roanoke River and its tributaries, extending from its mouth to Roanoke Rapids Dam, including the Cashie, Middle, and Eastmost rivers and their tributaries.

This Proclamation shall be effective at 12:01 a.m. 1 January 1993 and shall remain in effect until 12:00 p.m. 28 February 1993 or until a new proclamation opening the described waters or portions thereof for striped bass fishing is issued.

NOTES:

- a) This Proclamation is issued under the authority of N.C.G.S. §113-132; 113-134; 113-292; 113-304; and 113-305.
- b) All striped bass regardless of condition taken subsequent to the effective date and time of this Proclamation shall be immediately returned to the waters where taken and no striped bass may be possessed.
- c) Any person who violates this Proclamation also violates applicable law and is subject to the sanctions provided by law.

NORTH CAROLINA WILDLIFE RESOURCES COMMISSION

by \_\_\_\_\_  
Charles R. Fullwood  
Executive Director

## TITLE 10 - DEPARTMENT OF HUMAN RESOURCES

*Notice is hereby given in accordance with G.S. 150B-21.2 that the DHR/Division of Medical Assistance intends to amend rules cited as 10 NCAC 26B .0119 and .0121.*

*The proposed effective date of this action is April 1, 1993.*

*The public hearing will be conducted at 1:30 p.m. on February 5, 1993 at the North Carolina Division of Medical Assistance, 1985 Umstead Drive, Room 132, Raleigh, NC 27603.*

### **Reason for Proposed Action:**

**10 NCAC 26B .0119** - This amendment will bring Medicaid personal care services provider qualifications in line with State licensure requirements for providers of in-home aide services under the Home Care Licensure Act.

**10 NCAC 26B .0121** - This change is necessary to bring Medicaid private duty nursing provider qualifications in line with State licensure requirements for providers of nursing services under the Home Care Licensure Act.

**Comment Procedures:** Written comments concerning these amendment must be submitted by February 5, 1993, to: Division of Medical Assistance, 1985 Umstead Drive, Raleigh, NC 27603 ATTN: Clarence Ervin, APA Coordinator. Oral comments may be presented at the hearing. In addition, a fiscal impact statement is available upon written request from the same address.

## CHAPTER 26 - MEDICAL ASSISTANCE

### SUBCHAPTER 26B - MEDICAL ASSISTANCE PROVIDED

#### SECTION .0100 - GENERAL

#### **.0119 PERSONAL CARE SERVICES**

(a) The Division of Medical Assistance will cover personal care services in accordance with federal law. The provision of personal care services must be physician authorized and must meet the following criteria:

(1) The recipient of the service must have

a medical diagnosis that warrants a physician's care and that recipient must be under the direct and ongoing care of the physician prescribing PCS.

(2) The recipient's medical condition must be stable at maintenance level.

(3) There must be a medical necessity for the provision of personal care services.

(b) ~~Agencies which may be enrolled as providers of service include: county health departments; county departments of social services; certified home health agencies; hospice agencies enrolled in Medicaid; the State Division of Services for the Blind; agencies accredited through the Community Health Accreditation Program care organizations providing paraprofessional services; agencies accredited by the Joint Commission on Accreditation of Healthcare Organizations for meeting their Standards for the Accreditation of Home Care and specific quality standards for providers of personal care and support services; agencies accredited by the North Carolina Accreditation Commission for In Home Aide Services; and agencies approved by the National HomeCaring Council as meeting Basic National Standards for Homemaker/Home Health Aide Services. An enrolled provider must be a State licensed home care agency located within North Carolina that is approved in its license to provide in-home aide services.~~

Authority G.S. 108A-25(b); S.L. 1985, c. 479, s. 86; 42 C.F.R. 440.170(f).

#### **.0121 PRIVATE DUTY NURSING**

(a) Medically necessary private duty nursing (PDN) services are provided when they are prescribed by a physician and prior approved by the Division of Medical Assistance or its designee.

(b) A patient must reside in the patient's private residence to receive PDN services. Recipients who are in domiciliary care facilities (such as rest homes, group homes, family care homes, and similar settings) and those who are in hospitals, nursing facilities, intermediate care facilities for the mentally retarded, rehabilitation centers, and other institutional settings are not eligible for this service. PDN services are not covered while an individual is being observed or treated in a hospital emergency room or similar environment.

(c) Private duty nursing services are considered medically necessary when the person must require substantial and complex continuous nursing care by a licensed nurse. Professional judgment and a



thorough evaluation of the medical complexity and psychosocial needs of the patient are involved in determining the need for PDN. The following situations represent the usual types of cases that may require PDN, though the list is not meant to be all inclusive:

- (1) Patient requires prolonged intravenous nutrition or drug therapy with needs beyond those covered by infusion therapy services.
- (2) Patient is dependent on a ventilator for prolonged periods.
- (3) Patient is dependent on other device-based respiratory support, including tracheostomy care, suctioning, and oxygen support.

(d) This service is only approvable based on the need for PDN services in the patient's private residence. An individual with a medical condition that necessitates this service normally is unable to leave the home without being accompanied by a licensed nurse and leaving the home requires considerable and taxing effort. An individual may utilize the approved hours of coverage outside to his residence during those hours when the individual's normal life activities take the patient out of the home. The need for nursing care to participate in activities outside of the home is not a basis for authorizing PDN services or expanding the hours needed for PDN services.

(e) A person may not receive Personal Care Services, Skilled Nursing Visits, and Home Health Aide Services reimbursed by Medicaid during the same hours of the day as PDN services.

(f) The patient's spouse, child, parent, grandparent, grandchild, or sibling, including corresponding step and in-law relationship may not be employed by the provider agency when reimbursed by Medicaid to provide PDN services to the patient.

(g) Medicaid payments for PDN are made only to agencies enrolled with the Division of Medical Assistance as providers for the service. ~~An agency must be one of the following to be enrolled to provide this service:~~

- ~~(1) A Medicare certified home health agency located within North Carolina.~~
- ~~(2) A State licensed home health agency located within North Carolina.~~
- ~~(3) An agency with a North Carolina office that is accredited in the provision of in-home nursing care by either the Joint Commission on Accreditation of Health Care Organizations (JCAHO) or the~~

~~National League for Nursing (NLN).~~

An enrolled provider must be a State licensed home care agency located within North Carolina that is approved in its license to provide Nursing Services.

Authority G.S. 108A-25(b); 108A-54;42 C.F.R. 440.80.

\* \* \* \* \*

*Notice is hereby given in accordance with G.S. 150B-21.2 that the DHR/Division of Medical Assistance intends to amend rule cited as 10 NCAC 26D .0012 with changes from the proposed text noticed in the Register, Volume 7, Issue 12, page 1156.*

*The proposed effective date of this action is April 1, 1993.*

*Reason for Proposed Actions: The rule clarifies that the phrase "date of payment" and addresses Medicaid claims for which payment was denied.*

*Comment Procedures: Written comments concerning this amendment must be submitted by February 4, 1993, to: Division of Medical Assistance, 1985 Umstead Drive, Raleigh, NC 27603 ATTN: Clarence Ervin, APA Coordinator. In addition, a fiscal impact statement is available upon written request from the same address.*

*Editor's Note: An agency may not adopt a rule that differs substantially from the text of a proposed rule published in the Register, unless the agency publishes the text of the proposed different rule and accepts comments on the new text for at least 30 days after the publication of the new text.*

## SUBCHAPTER 26D - LIMITATIONS ON AMOUNT: DURATION: AND SCOPE

### .0012 TIME LIMITATION

(a) To receive payment, claims must be filed either received for processing:

- (1) Within 365 days of the date of service for services other than inpatient hospital, home health or nursing home services; or
- (2) Within 365 days of the date of

discharge for inpatient hospital services and the last date of service in the month for home health and nursing home services not to exceed the limitations as specified in 42 C.F.R. 447.45; or

- (3) Within 180 days of the Medicare or other third party payment, or within 180 days of final denial, when the date of the third party payment or denial exceeds the filing limits in Paragraphs (1) or (2) of this Rule, except that the time limit may not be waived under this Paragraph when the claim is denied because it was not submitted to the third party timely, the service was not a covered service by the third party, the individual was not enrolled with the third party or the claim was paid or denied at an earlier date.

(b) Providers must file requests for payment adjustments or requests for reconsideration of a denied claim no later than 18 months after the date of payment or denial of a claim. ~~or adjustments will not be made.~~

(c) The time limitation specified in (a) of this Rule may be waived by the Division of Medical Assistance when ~~an delay in an~~ eligibility determination, has made it impossible for the provider to file the claim within the 365 days provided for in (a) of this Rule correction of an administrative error in determining eligibility, application of a court order or hearing decision grants eligibility with less than 60 days for providers to submit claims for eligible dates of service provided the claims is received for processing within 180 days after the date the county department of Social Services approves the eligibility.

(d) In cases where claims or adjustments were not filed within the time limitations specified in (a) and (b) of this Rule, and the provider shows failure to do so was beyond his control, he may request a reconsideration review by the Director of the Division of Medical Assistance. The Director of Medical Assistance is the final authority for reconsideration reviews. If the provider wishes to contest this decision, he may do so by filing a petition for a contested case hearing in conformance with G.S. 150B-23.

*Authority G.S. 108A-25(b); 42 C.F.R. 447.45.*

TITLE 15A - DEPARTMENT OF

**ENVIRONMENT, HEALTH, AND  
NATURAL RESOURCES**

*Notice is hereby given in accordance with G.S. 150B-21.2 that the Environmental Management Commission intends to amend rule cited as 15A NCAC 2D .1002.*

*The proposed effective date of this action is June 1, 1993.*

*The public hearing will be conducted at 7:00 p.m. on February 3, 1993 at the Guilford County Courthouse, Courtroom 2A, 210 South Eugene Street, Greensboro, NC.*

*Reason for Proposed Action: To remove requirement for an inspection/maintenance program in Davidson and Randolph Counties.*

*Comment Procedures: All persons interested in this matter are invited to attend the public hearing. Any person desiring to comment for more than three minutes at the public hearing is requested to submit a written statement for inclusion in the record of proceedings. The hearing officer may limit oral presentation lengths to five minutes if many people want to speak. The record of proceedings will remain open until March 1, 1993, to receive additional written statements. To be included, the statement must be received by the Department by March 1, 1993.*

*Comments should be sent to and additional information concerning the hearing or the proposals may be obtained by contacting: Mr. Thomas C. Allen, Division of Environmental Management, P.O. Box 29535, Raleigh, North Carolina 27626-0535, (919) 733-1489.*

*Editor's Note: This Rule was filed as a temporary amendment to delete Davidson County in Paragraph (a) and the addition of Paragraph (c). The deletion of Randolph County in Paragraph (a) was not a part of the temporary filing. The effective date of the temporary amendment is January 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner.*

**CHAPTER 2 - ENVIRONMENTAL MANAGEMENT**

**SUBCHAPTER 2D - AIR POLLUTION CONTROL REQUIREMENTS**

**SECTION .1000 - MOTOR VEHICLE EMISSION CONTROL STANDARD**

**.1002 APPLICABILITY**

(a) This Section is applicable to all 1975 and later gasoline-powered motor vehicles, except motorcycles and excluding the current model year, that are required to be registered by the North Carolina Division of Motor Vehicles in the counties listed in Paragraph (b) of this Rule.

(b) The emission standards will become effective in the following counties on the dates indicated below:

<u>County</u>	<u>Effective Date</u>
Mecklenburg	April 1, 1991
Wake	April 1, 1991
Forsyth	July 1, 1991
Guilford	July 1, 1991
Durham	July 1, 1992
Gaston	July 1, 1992
Davidson	January 1, 1993

Cabarrus	January 1, 1993
Randolph	July 1, 1993
Orange	July 1, 1993
Union	July 1, 1993

(c) If the United States Environmental Protection Agency does not redesignate Davidson, Forsyth, and Guilford Counties and the portion of Davie County that is nonattainment for ozone as attainment areas for ozone, then emission standards and requirements of this Section shall become effective in Davidson and Randolph Counties within six months of formal notification by EPA.

Statutory Authority G.S. 20-128.2(a); 143-215.3(a)(1); 143-215.107(a)(3); 143-215.107(a)(6); 143-215.107(a)(7).

\*\*\*\*\*

**Notice** is hereby given in accordance with G.S. 150B-21.2 that the EHNR - Radiation Protection Commission intends to adopt rules cited as 15A NCAC 11 .0117, amend rules cited as 15A NCAC 11 .0101 - .0102, .0105 - .0108, .0111, .0113 - .0115, .0201, .0205, .0207, .0210, .0212 - .0214, .0303 - .0305, .0318, .0321, .0324 - .0326, .0337 - .0338, .0343 - .0346, .0352, .0501, .0507, .0510, .0518, .0602, .0605 - .0606, .0701, .0703, .0902, .1001, .1006, .1102 - .1104, .1202 - .1203, .1205, .1210, .1215, .1218, .1220 - .1221, .1223, .1227, .1229, .1239 - .1240, .1306, .1308 - .1310, .1313 and repeal rule cited as 15A NCAC 11 .0336.

**The** proposed effective date of this action is May 3, 1993.

**Instructions on How to Demand a Public Hearing** (must be requested in writing within 15 days of notice): Any person requesting that the Division of Radiation Protection hold a public hearing on these rules must submit a written request by January 19, 1993. The request must be submitted to Richard M. Fry, Deputy Director, Division of Radiation Protection, P. O. Box 27687, Raleigh, NC 27611-7687.

**Reason for Proposed Action:** Corrects misspelled words; removes obsolete Subparagraph numbers; corrects agency telephone number; adopts federal citations by reference in Rule .0117; and Rule .0336 is being repealed as information is now contained in Rule .0117.

**Comment Procedures:** Written comments should be submitted to the Division of Radiation Protec-

tion, P. O. Box 27687, Raleigh, NC 27611-7687. Written comments will be accepted until February 3, 1993. Any person requesting information concerning these rules should contact Richard M. Fry at 919/571-4141.

## CHAPTER 11 - RADIATION PROTECTION

### SECTION .0100 - GENERAL PROVISIONS

#### .0101 SCOPE

(a) Except as otherwise specifically provided these ~~Regulations~~ Rules apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation within the State of North Carolina.

(b) Nothing in these ~~Regulations~~ Rules shall apply to any person to the extent any person is subject to regulation by the United States Nuclear Regulatory Commission.

(c) Regulation by the State of North Carolina of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of an agreement made between the Governor of this state and the United States Nuclear Regulatory Commission under provisions of Public Law 86-373, as amended, and to 10 CFR Part 150.

Statutory Authority G.S. 104E-2; 104E-7; 104E-10.

#### .0102 COMPLIANCE WITH LAWS

Nothing in these ~~Regulations~~ Rules shall relieve any person of responsibility for complying with other pertinent North Carolina laws, rules and regulations.

Statutory Authority G.S. 104E-7.

#### .0105 OTHER DEFINITIONS

Definitions of certain other words and phrases as used in these ~~Regulations~~ Rules are set forth in

Sections .0500, .0600, .0800, .1200, .1300, and .1400, and .1500 of this Chapter.

*Statutory Authority G.S. 104E-7.*

#### **.0106 EXEMPTIONS**

(a) The agency may, upon application therefore, grant individual exemptions or exceptions from the requirements of these Regulations Rules as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(b) Except as otherwise provided in this Rule, common and contract or other carriers, freight forwarders, and warehousemen, who are subject to the rules and regulations of the U.S. Postal Service (39 CFR Parts 14 and 15), are exempt from these Regulations Rules to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto. Common, contract, or other carriers who are not exempt pursuant to this Rule are subject to the provisions of Rule .0316 of this Chapter. Notwithstanding these exemptions, common, contract or other carriers are required to comply with the provisions of Rule .0316(c) of this Chapter to the extent that these carriers are transporting spent nuclear fuel, as defined in Rule .0316(c) of this Chapter, upon the highways of North Carolina.

(c) Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these Regulations to the extent that the contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

- (1) prime contractors performing work for the U.S. Department of Energy at U.S. government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;
- (2) prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;
- (3) prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other

nuclear devices in a United States government-owned vehicle or vessel; and

- (4) any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the agency and the U.S. Nuclear Regulatory Commission jointly determine that:
  - (A) the exemption of the prime contractor or subcontractor is authorized by law,
  - (B) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

*Statutory Authority G.S. 104E-2; 104E-7; 104E-15.*

#### **.0107 INSPECTIONS**

Each licensee and registrant shall, upon reasonable notice, make available to the agency for inspection records maintained pursuant to provisions of these Regulations Rules.

*Statutory Authority G.S. 104E-7; 104E-11(a).*

#### **.0108 ADDITIONAL REQUIREMENTS**

(a) The agency may, by license condition, registration condition, or order, when not in conflict with any law, impose upon any specific or general licensee or registrant such requirements in addition to those established in these Regulations Rules as it deems appropriate or necessary to minimize danger to public health, safety or property. Such additional requirements are subject to appeal procedures contained in Section 15A NCAC 1B .0200.

(b) The Commission may by rule or regulation require radioactive material licensees to procure and file with the department such bond, insurance or other security as the Commission deems necessary to protect the state from costs for emergency response and perpetual maintenance.

*Statutory Authority G.S. 104E-7; 104E-18.*

#### **.0111 COMMUNICATIONS**

(a) Except as provided in Paragraph (b) of this Rule, all AH communications and reports concerning these Rules, and applications filed thereunder, shall be mailed to the agency at Division of Radiation Protection, P.O. Box 27687, Raleigh, North Carolina 27611-7687 or delivered

to the agency at its office located at 3825 Barrett Drive, Raleigh, North Carolina 27609-7221.

(b) Except as specifically instructed otherwise by the agency, immediate telephone notification and reports required by the rules in this Chapter shall be directed to (919) 571-4141 from 8:00 a.m. to 5:30 p.m. on workdays.

*Statutory Authority G.S. 104E-7.*

### **.0113 CLASSIFICATION OF RADIOACTIVE MATERIAL**

For a single radionuclide of known identity, the values of  $A_1$  and  $A_2$  used for determining Type A quantity in the Rules of this Chapter are taken from Appendix A of 10 CFR 71 as revised at 48 Federal Register 35600, August 5, 1983, and corrections at 48 Federal Register 38449, August 24, 1983.

*Statutory Authority G.S. 104E.*

### **.0114 TESTS FOR SPECIAL FORM**

Special form radioactive material as defined in Rule .0104(56) of this Section must satisfactorily pass the following tests:

- (1) a free drop through a distance of 30 feet onto a flat essentially unyielding horizontal surface, striking the surface in such a position as to suffer maximum damage;
- (2) impact of the flat circular end of a one-inch diameter steel rod weighing three pounds, dropped through a distance on a sheet of lead, of hardness number 3.5 to 4.5 on the Vickers scale, and not more than one inch thick supported by a smooth essentially unyielding surface;
- (3) heating in air to a temperature of 1,475° F. and remaining at that temperature for a period of ten minutes;
- (4) immersion for 24 hours in water at room temperature at pH 6 to pH 8, with a maximum conductivity of ten micromhos per centimeter.

*Statutory Authority G.S. 104E-15.*

### **.0115 RECORDS**

Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these Regulations Rules.

*Statutory Authority G.S. 104E-7; 104E-12(a).*

### **.0117 FEDERAL RULES INCORPORATED BY REFERENCE**

(a) For the purpose of the rules in this Chapter, the following federal regulations are hereby incorporated by reference including any subsequent amendments and editions:

- (1) Appendix A, Appendix B and Appendix C to 10 CFR Parts 20.1001 - 20.2401;
- (2) 10 CFR Part 31, 10 CFR Part 32 and 10 CFR Part 40;
- (3) 10 CFR Part 61, 10 CFR Part 70, 10 CFR Part 71, 10 CFR Part 73, 10 CFR Part 110, 10 CFR Part 140 and 10 CFR Part 150;
- (4) 21 CFR Part 1010, 21 CFR Part 1020 and 21 CFR Part 1040;
- (5) 39 CFR Part 14 and 39 CFR Part 15;
- (6) Postal Service Manual (Domestic Mail Manual) Section 124.3 [incorporated by reference in 39 CFR Section 111.11];
- (7) 40 CFR Part 261; and
- (8) 49 CFR Parts 100-189.

(b) The regulations incorporated by reference in Paragraph (a) of this Rule are available for inspection at the Department of Environment, Health, and Natural Resources, Division of Radiation Protection at the address listed in Rule .0111 of this Section. Except as noted in Subparagraph (b)(1) of this Rule, copies of the regulations incorporated by reference in Paragraph (a) of this Rule may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 at a cost as follows:

- (1) \$5.00 for the appendices listed in Subparagraph (a)(1) of this Rule, available from the Division of Radiation Protection at the address listed in Rule .0111 of this Section;
- (2) \$25.00 for the regulations listed in Subparagraph (a)(2) of this Rule in a volume containing 10 CFR Parts 0-50;
- (3) \$18.00 for the regulations listed in Subparagraph (a)(3) of this Rule in a volume containing 10 CFR Parts 51-199;
- (4) \$18.00 for the regulations listed in Subparagraph (a)(4) of this Rule in a volume containing 21 CFR Parts 800-1299;
- (5) \$16.00 for the regulations listed in Subparagraph (a)(5) of this Rule in a volume containing 39 CFR;
- (6) \$36.00 for the manual listed in Subparagraph (a)(6) of this Rule;
- (7) \$31.00 for the regulations listed in

Subparagraph (a)(7) of this Rule in a volume containing 40 CFR Parts 260-299; and

(8) for the regulations listed in Subparagraph (a)(8) of this Rule;

(A) \$23.00 for a volume containing 49 CFR Parts 100-177; and

(B) \$17.00 for a volume containing 49 CFR Parts 178-199.

*Statutory Authority G.S. 104E-7; 104E-15(a); 150B-21.6.*

## **SECTION .0200 - REGISTRATION OF RADIATION MACHINES: FACILITIES AND SERVICES**

### **.0201 PURPOSE AND SCOPE**

(a) This Section provides for the registration of radiation machines, radiation machine facilities and persons who provide other radiological services.

(b) For purposes of this Section, "facility" means the location at which one or more radiation machines are installed or located within one building, vehicle, or under one roof and are under the same administrative control.

(c) In addition to the requirements of this Section, all registrants are subject to the provisions of the other sections of this Chapter.

(d) Special requirements for registration of particle accelerators are provided in Section .0900 of this Chapter and are in addition to the requirements ~~in~~ of this Section.

(e) In addition to the requirements of this Section, all registrants are subject to the annual fee provisions contained in Section .1100 of this Chapter.

*Statutory Authority G.S. 104E-7; 104E-9(8); 104E-19(a).*

### **.0205 APPLICATION FOR REGISTRATION OF SERVICES**

(a) Each person who is engaged in the business of installing or offering to install radiation machines and machine components or is engaged in the business of furnishing or offering to furnish any equipment services listed in Paragraph (d) of this Rule in this state, to any agency licensee or registrant, shall apply for registration of such services with the agency within 30 days following the amended effective date of this Rule or thereafter prior to furnishing or offering to furnish any of these services.

(b) Application for registration shall be

completed on appropriate form(s) provided by the agency and shall contain all information required by the agency as indicated on the form and accompanying instructions. This information shall include:

(1) the name, address and telephone number of:

(A) the individual or the company to be registered;

(B) the owner(s) of the company;

(2) the description of the services to be provided;

(3) the name, training and experience of each person who provides services specified in Paragraph (d) of this Rule;

(4) the date of the application and the signature of the person responsible for the company; and

(5) any additional information the agency determines to be necessary for evaluation of the application for registration.

(c) Each person applying for registration under Paragraph (a) of this Rule shall certify that he has read and understands the requirements of the ~~Rules~~ rules in this Chapter.

(d) For the purpose of this Section, equipment services are:

(1) direct sale and transfer of radiation machines and machine components to end users;

(2) installation or servicing of radiation machines and associated radiation machine components;

(3) diagnostic radiographic facility and shielding design;

(4) diagnostic fluoroscopic facility and shielding design;

(5) diagnostic area radiation survey, e.g., shielding evaluation;

(6) radiation instrument calibration;

(7) therapeutic facility and shielding design, area radiation survey or calibration;

(8) personnel dosimetry services;

(9) general health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, non-healing arts facility and shielding design and area radiation surveys; and

(10) such other equipment services which can affect compliance with these Rules by a licensee or registrant, as

determined by the agency.

(e) Applicants for registration of services are subject to the applicable requirements of Rules .0213 and .0214 of this Section.

*Statutory Authority G.S. 104E-7.*

#### **.0207 ISSUANCE OF NOTICE OF REGISTRATION**

(a) The agency shall issue a notice of registration upon a determination that an applicant:

- (1) is qualified by reason of education, training and experience;
- (2) has adequate facilities and equipment;
- (3) has established an adequate radiation protection program appropriate to the registered activities; and
- (4) meets the applicable requirements in this Chapter.

(b) The agency may incorporate in the notice of registration at the time of issuance or thereafter by amendment or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation machines as the agency deems appropriate or necessary for compliance with the rules in this Chapter. Such additional requirements are subject to appeal under 15A NCAC 1B .0200.

(c) The agency may refuse to grant a registration required in Rules .0203 and .0205 of this Section to any applicant who does not possess adequate qualifications or equipment or satisfy the applicable requirements in this Chapter; provided that, before any order is entered denying an application for registration, the agency shall give notice and grant a hearing as provided in Chapter 150B of the North Carolina General ~~Statutes~~ Statutes.

*Statutory Authority G.S. 104E-7.*

#### **.0210 OTHER PROHIBITED ACTIVITIES**

(a) No person registered pursuant to Rule .0205 of this Section for x-ray sales or installations shall make, sell, lease, transfer, lend, assemble, or install radiation machines or equipment used in connection with such machines unless such machines and equipment when placed in operation shall meet the applicable requirements of these Regulations Rules.

(b) No person, in any advertisement, shall refer to the fact that he or his facility is registered with the agency pursuant to the provisions of Rule .0203 or .0205 of this Section and no person shall state or imply that any activity under such

registration has been approved by the agency.

(c) No person registered pursuant to Rule .0205 of this Section shall install radiation machines which are subject to provisions of Section .0600 of this Chapter unless the registrant first determines that the agency has issued written acknowledgement of receipt of any facility and shielding design required in Rule .0603 of this Chapter.

*Statutory Authority G.S. 104E-7; 104E-20.*

#### **.0212 MODIFICATIONS: REVOCATION: TERMINATION OF REGISTRANTS**

(a) The terms and conditions of all registrations are subject to amendment, revision or modification and all registrations are subject to suspension or revocation by reason of:

- (1) amendments to the Act;
- (2) rules adopted pursuant to provisions of the Act; or
- (3) orders issued by the agency pursuant to provisions of the Act and rules adopted pursuant to provisions of the Act.

(b) Any registration may be revoked, suspended or modified in whole or in part:

- (1) for any material false statement in the application or in any statement of fact required by provisions of this Section;
- (2) because of conditions revealed by:
  - (A) the application;
  - (B) any statement of fact;
  - (C) any report, record, inspection or other means, which would warrant the agency to refuse to grant a registration on original application; or
- (3) for violations of, or failure to observe any of the terms and conditions of the Act, the registration, the ~~Rules~~ rules of this Chapter, or order of the agency.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for modification, revocation or suspension of a registrant, the agency shall:

- (1) call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and
- (2) provide an opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.

(d) Before any order is entered suspending, revoking or modifying a registration, the agency shall give notice and grant a hearing as provided in



Chapter 150B of the North Carolina General Statutes.

(e) The agency may terminate a registration upon written request submitted by the registrant to the agency.

*Statutory Authority G.S. 104E-7.*

**.0213 ADDITIONAL REQUIREMENTS:  
REGISTERED SERVICES**

(a) An applicant for registration of diagnostic area radiation survey, diagnostic radiation output measurements or therapeutic calibration services pursuant to Rule .0205 of this Section shall meet the following additional requirements:

- (1) The applicant shall have adequate radiation survey and radiation measurement equipment appropriate to the services requested for authorization.
- (2) The applicant shall ensure that the equipment in Subparagraph (a)(1) of this Rule is calibrated at least every 12 months by persons registered to provide such services pursuant to Rule .0205 of this Section, except as provided in Subparagraph (a)(3) of this Rule. The agency may approve less frequent calibration of equipment used for therapy calibration, provided the applicant satisfies the agency that the proposed frequency and procedures will provide equivalent or better assurance of proper calibration.
- (3) The applicant may perform the equipment calibrations required in Subparagraph (a)(2) of this Rule provided that:
  - (A) such calibrations are currently traceable to the National Institute of Standards and Technology;
  - (B) the calibration procedures are approved by the agency;
  - (C) the radiation sources used for such calibration are licensed or registered as required by the Rules rules in this Chapter; and
  - (D) the equipment is labeled to indicate the date of calibration and records of the calibration are maintained.
- (4) The applicant shall submit, for approval by the agency:
  - (A) a description of the procedures that will be utilized in performing area radiation surveys including a list of all guides and references to the

employed;

- (B) a copy of all forms, reports and documents that will be supplied to customers;
- (C) samples of three different types of surveys;
- (D) samples of three reports of diagnostic radiation output measurements; and
- (E) samples of three therapeutic calibration reports.

(b) An applicant for registration of services pursuant to Rule .0205 of this Section who proposes to provide diagnostic radiographic, fluoroscopic and therapeutic facility and shielding design services shall meet the following additional requirements:

- (1) The applicant shall submit, for approval by the agency, examples of the facility and shielding design which will be provided to clients.
- (2) The applicant shall submit examples of the calculations which will be performed as part of the facility and shielding design along with any guides, occupancy factor rationales, and workload estimation rationales which will be used.
- (3) The applicant shall ensure that the facility and shielding design services provided to licensees and registrants of the agency satisfy the applicable requirements in this Chapter.

*Statutory Authority G.S. 104E-7.*

**.0214 TRAINING AND EDUCATIONAL  
REQUIREMENTS FOR EQUIPMENT  
SERVICES**

(a) Each person registered pursuant to Rule .0205 of this Section shall be qualified by reason of education, training and experience to provide the services for which registration is requested. The following are minimum qualifications for specific types of services:

- (1) Class I - sales of radiation machines and machine components to end users: The applicant must certify knowledge of familiarity with the Rules rules and Regulations regulations which govern the possession, installation and use of radiation machines in North Carolina.
- (2) Class II - installation and service of radiation machines and machine components including the making of diagnostic radiation output

measurements to verify performance associated with the installation or service:

- (A) manufacturer's equipment school for service, maintenance and installation for the type of machine use (e.g. dental intraoral, medical diagnostic or medical fluoroscopic) or equivalent training;
  - (B) training in principles of radiation protection; and
  - (C) three to six months of experience in installation and service of radiation machines and machine components.
- (3) Class III - diagnostic radiographic facility and shielding design:
- (A) formalized training in principles of radiation protection;
  - (B) formalized training in shielding design; and
  - (C) one year of experience in diagnostic radiographic facility and shielding design for the specific type of machine application.
- (4) Class IV - diagnostic fluoroscopic facility and shielding design:
- (A) formalized training in principles of radiation protection;
  - (B) formalized training in shielding design; and
  - (C) one year of experience in diagnostic fluoroscopic facility and shielding design for the specific type of machine application.
- (5) Class V - diagnostic area radiation survey, e.g., shielding evaluation:
- (A) formalized training in basic radiological health;
  - (B) formalized training in shielding evaluation; and
  - (C) one year of experience performing area radiation surveys.
- (6) Class VI - radiation instrument calibration: The applicant must possess a current radioactive materials license or registration authorizing radiation instrument calibration.
- (7) Class VII - therapeutic facility and shielding design, area radiation survey, or calibration:
- (A) certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics;

or certification by the American Board of Medical Physics; or

- (B) having the following minimum training and experience:
    - (i) a master's degree in physics, biophysics, radiological physics or health physics;
    - (ii) one year of full-time training in therapeutic radiological physics
    - (iii) one year of full-time experience in a therapeutic facility including personal calibration and spot-check of at least one machine;
  - (C) shall submit a description of the procedures that will be utilized in performing therapeutic calibrations including a list of all guides and references to be employed;
  - (D) shall submit a copy of all forms, reports and documents that will be supplied to customers; and
  - (E) shall submit one sample of each specific type, e.g., teletherapy, accelerator.
- (8) Class VIII - personnel dosimetry service: The applicant must hold current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology or use NVLAP accredited dosimetry.
- (9) Class IX - general health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs, and radiation safety training programs, non-healing arts facility and shielding design, and area radiation surveys:
- (A) baccalaureate degree in a physical science (e.g. physics, chemistry or radiologic science), engineering or related field and two years of progressive experience in medical or health physics; graduate training in medical or health physics may be substituted on a year for year basis; or
  - (B) certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; certification by the American Board

of Health Physics in health physics or certification by the American Board of Medical Physics.

(b) Any person not meeting the requirements in Paragraph (a) of this Rule may apply to the agency for registration, provided such person demonstrates education, training and experience which is equivalent to that required in Paragraph (a) of this Rule.

(c) Any person registered prior to the effective date of this Rule to provide equipment services pursuant to Rule .0205 of this Section shall meet the education, training and experience requirements in Paragraph (a) or (b) of this Rule no later than 24 months after the effective date of this Rule.

(d) The agency shall initiate action to terminate the registration of any person who fails to comply with the requirements of Paragraph (c) of this Rule.

*Statutory Authority G.S. 104E-7.*

## SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL

### .0303 EXEMPT CONCENTRATIONS: OTHER THAN SOURCE MATERIAL

(a) No person shall introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under Paragraph (b) of this Rule or equivalent regulations of the U.S. Nuclear Regulatory Commission or any agreement state, except in accordance with a specific license issued pursuant to Rule .0325 of this Section.

(b) Except as provided in Paragraph (a) of this Rule, any person is exempt from these ~~Regulations~~ Rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires products or materials containing radioactive material in concentrations not in excess of those listed in the following table:

#### EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration microcurie/ml	Column II Liquid and solid concentration microcurie/ml
Antimony (51)	S <del>B</del> b 122		3X10 <sup>-4</sup>
	Sb 124		2X10 <sup>-4</sup>
	Sb 125		1X10 <sup>-3</sup>
Argon (18)	Ar 37	1X10 <sup>-3</sup>	
	Ar 41	4X10 <sup>-7</sup>	
Arsenic (33)	As 73		5X10 <sup>-3</sup>
	As 74		5X10 <sup>-4</sup>
	As 76		2X10 <sup>-4</sup>
	As 77		8X10 <sup>-4</sup>
Barium (56)	Ba 131		2X10 <sup>-3</sup>
	Ba 140		3X10 <sup>-4</sup>

**PROPOSED RULES**

Beryllium (4)	Be 7		2X10 <sup>-2</sup>
Bismuth (83)	Bi 206		4X10 <sup>-4</sup>
Bromine (35)	Br 82	4X10 <sup>-7</sup>	3X10 <sup>-3</sup>
Cadmium (48)	Cd 109		2X10 <sup>-3</sup>
	Cd 115m		3X10 <sup>-4</sup>
	Cd 115		3X10 <sup>-4</sup>
Calcium (20)	Ca 45		9X10 <sup>-5</sup>
	Ca 47		5X10 <sup>-4</sup>
Carbon (6)	C 14	1X10 <sup>-6</sup>	8X10 <sup>-3</sup>
Cerium (58)	Ce 141		9X10 <sup>-4</sup>
	Ce 143		4X10 <sup>-4</sup>
	Ce 144		1X10 <sup>-4</sup>
Cesium (55)	Cs 131		2X10 <sup>-2</sup>
	Cs 134m		6X10 <sup>-2</sup>
	Cs 134		9X10 <sup>-5</sup>
Chlorine (17)	Cl 38	9X10 <sup>-7</sup>	4X10 <sup>-3</sup>
<del>4X10<sup>-3</sup></del>			
Chromium (24)	Cr 51		2X10 <sup>-2</sup>
Cobalt (27)	Co 57		5X10 <sup>-3</sup>
	Co 58		1X10 <sup>-3</sup>
	Co 60		5X10 <sup>-4</sup>
Copper (29)	Cu 64		3X10 <sup>-3</sup>
Dysprosium (66)	Dy 165		4X10 <sup>-3</sup>
	Dy 166		4X10 <sup>-4</sup>
Erbium (68)	Er 169		9X10 <sup>-4</sup>
	Er 171		1X10 <sup>-3</sup>
Europium (63)	Eu 152		6X10 <sup>-4</sup>
	(T <sub>1/2</sub> T <sub>1/2</sub> =9.2 Hrs.)		
	Eu 155		2X10 <sup>-3</sup>
Fluorine (9)	F 18	2X10 <sup>-6</sup>	8X10 <sup>-3</sup>
Gadolinium (64)	Gd 153		2X10 <sup>-3</sup>
	Gd 159		8X10 <sup>-4</sup>
Gallium (31)	Ga 72		4X10 <sup>-4</sup>
Germanium (32)	Ge 71		2X10 <sup>-2</sup>
Gold (79)	Au 196		2X10 <sup>-3</sup>
	Au 198		5X10 <sup>-4</sup>
	Au 199		2X10 <sup>-3</sup>
Hafnium (72)	Hf 181		7X10 <sup>-4</sup>
Hydrogen (1)	H 3	5X10 <sup>-6</sup>	3X10 <sup>-2</sup>
Indium <del>(40)</del> (49)	In 113m		1X10 <sup>-2</sup>
	In 114m		2X10 <sup>-4</sup>
Iodine (53)	I 126	3X10 <sup>-9</sup>	2X10 <sup>-5</sup>
	I 131	3X10 <sup>-9</sup>	2X10 <sup>-5</sup>
	I 132	8X10 <sup>-8</sup>	6X10 <sup>-4</sup>
	I 133	1X10 <sup>-8</sup>	7X10 <sup>-5</sup>
	I 134	2X10 <sup>-7</sup>	1X10 <sup>-3</sup>
Iridium (77)	Ir 190		2X10 <sup>-3</sup>
	Ir 192		4X10 <sup>-4</sup>
	Ir 194		3X10 <sup>-4</sup>
Iron (26)	Fe 55		8X10 <sup>-3</sup>
	Fe 59		6X10 <sup>-4</sup>
Krypton (36)	Kr 85m		1X10 <sup>-6</sup>
	Kr 85		3X10 <sup>-6</sup>
Lanthanum (57)	La 140		2X10 <sup>-4</sup>
Lead (82)	Pb 203		4X10 <sup>-3</sup>

**PROPOSED RULES**

Lutetium (71)	Lu 177	1X10 <sup>-3</sup>
Manganese (25)	Mn 52	3X10 <sup>-4</sup>
	Mn 54	1X10 <sup>-3</sup>
	Mn 56	1X10 <sup>-3</sup>
	Hg 197m	2X10 <sup>-3</sup>
Mercury (80)	Hg 197	3X10 <sup>-3</sup>
	Hg 203	2X10 <sup>-4</sup>
	Mo 99	2X10 <sup>-3</sup>
Molybdenum (42)	Nd 147	6X10 <sup>-3</sup>
Neodymium (60)	Nd 149	3X10 <sup>-4</sup>
	Ni 65	1X10 <sup>-3</sup>
Nickel (28)		
Niobium		
(Columbium)(41)	Nb 95	1X10 <sup>-3</sup>
	Nb 97	9X10 <sup>-3</sup>
Osmium (76)	Os 185	7X10 <sup>-4</sup>
	Os 191m	3X10 <sup>-2</sup>
	Os 191	2X10 <sup>-3</sup>
	Os 193	6X10 <sup>-4</sup>
Palladium (46)	Pd 103	3X10 <sup>-3</sup>
	Pd 109	9X10 <sup>-4</sup>
Phosphorus (15)	P 32	2X10 <sup>-4</sup>
Platinum (78)	Pt 191	1X10 <sup>-3</sup>
	Pt 193m	1X10 <sup>-2</sup>
	Pt 197m	1X10 <sup>-2</sup>
	Pt 197	1X10 <sup>-3</sup>
Polonium (84)	Po 210	7X10 <sup>-6</sup>
Potassium (19)	K 42	3X10 <sup>-3</sup>
Praseodymium (59)	Pr 142	3X10 <sup>-4</sup>
	Pr 143	5X10 <sup>-4</sup>
Promethium (61)	Pm 147	2X10 <sup>-3</sup>
	Pm 149	4X10 <sup>-4</sup>
Radium (88)	Ra 226	1X10 <sup>-7</sup>
	Ra 228	3X10 <sup>-7</sup>
Rhenium (75)	Re 183	6X10 <sup>-3</sup>
	Re 186	9X10 <sup>-4</sup>
	Re 188	6X10 <sup>-4</sup>
Rhodium (45)	Rh 103m	1X10 <sup>-1</sup>
	Rh 105	1X10 <sup>-3</sup>
Rubidium (37)	Rb 86	7X10 <sup>-4</sup>
Ruthenium (44)	Ru 97	4X10 <sup>-3</sup>
	Ru 103	8X10 <sup>-4</sup>
	Ru 105	1X10 <sup>-3</sup>
	Ru 106	1X10 <sup>-4</sup>
Samarium (62)	Sm 153	8X10 <sup>-4</sup>
Scandium (21)	Sc 46	4X10 <sup>-4</sup>
	Sc 47	9X10 <sup>-4</sup>
	Sc 48	3X10 <sup>-4</sup>
Selenium (34)	Se 75	3X10 <sup>-3</sup>
Silicon (14)	Si 31	9X10 <sup>-3</sup>
Silver (47)	Ag 105	1X10 <sup>-3</sup>
	Ag 110m	3X10 <sup>-4</sup>
	Ag 111	4X10 <sup>-4</sup>
Sodium (11)	Na 24	2X10 <sup>-3</sup>
Strontium (38)	Sr 85	1X10 <sup>-3</sup>
	Sr 89	1X10 <sup>-4</sup>

**PROPOSED RULES**

	Sr 91		$7 \times 10^{-4}$
	Sr 92		$7 \times 10^{-4}$
Sulfur (16)	S 35	$9 \times 10^{-8}$	$6 \times 10^{-4}$
Tantalum (73)	Ta 182		$4 \times 10^{-4}$
Technetium (43)	Tc 96m		$1 \times 10^{-1}$
	Tc 96		$1 \times 10^{-3}$
Tellurium (52)	Te 125m		$2 \times 10^{-3}$
	Te 127m		$6 \times 10^{-4}$
	Te 127		$3 \times 10^{-3}$
	Te 129m		$3 \times 10^{-4}$
	Te 131m		$6 \times 10^{-4}$
	Te 132		$3 \times 10^{-4}$
Terbium (65)	Tb 160		$4 \times 10^{-4}$
Thallium (81)	Tl 200		$4 \times 10^{-3}$
	Tl 201		$3 \times 10^{-3}$
	Tl 202		$1 \times 10^{-3}$
	Tl 204		$1 \times 10^{-3}$
Thulium (69)	Tm 170		$5 \times 10^{-4}$
	Tm 171		$5 \times 10^{-3}$
Tin (50)	Sn 113		$9 \times 10^{-4}$
	Sn 125		$2 \times 10^{-4}$
Tungsten(Wolfram) (74)	W 181		$4 \times 10^{-3}$
	W 187		$7 \times 10^{-4}$
Vanadium (23)	V 48		$3 \times 10^{-4}$
Xenon (54)	Xe 131m	$4 \times 10^{-6}$	
	Xe 133	$3 \times 10^{-6}$	
	Xe 135	$1 \times 10^{-6}$	
Ytterbium (70)	Yb 175		$1 \times 10^{-3}$
Yttrium (39)	Y 90		$2 \times 10^{-4}$
	Y 91m		$3 \times 10^{-2}$
	Y 91		$3 \times 10^{-4}$
	Y 92		$6 \times 10^{-4}$
	Y 93		$3 \times 10^{-4}$
Zinc (30)	Zn 65		$1 \times 10^{-3}$
	Zn 69m		$7 \times 10^{-4}$
	Zn 69		$2 \times 10^{-2}$
Zirconium (40)	Zr 95		$6 \times 10^{-4}$
	Zr 97		$2 \times 10^{-4}$
Beta and/or gamma emitting radioactive material not listed above with half-life less than 3 years		$1 \times 10^{-10}$	$1 \times 10^{-6}$

(c) In Column I of the table, in Paragraph (b) of this Rule, values are given only for those materials normally used as gases.

(d) In Column II of the table, in Paragraph (b) of this Rule, the units, microcuries per gram, are used for solids.

(e) Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Paragraph (b) of this Rule, the activity stated is that of the parent isotope and takes into account the daughters.

(f) For purposes of this Rule, where a combination of isotopes is involved, the limit for the combination shall be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Paragraph (b) of this Rule for the specific isotope when not in combination. The sum of the ratios shall not exceed unity. An example of this is:

Concentration of Isotope A in Product

Exempt concentration of Isotope A

+

Concentration of Isotope B in Product

Exempt concentration of Isotope B

less than or equal to 1

*Statutory Authority G.S. 104E-7; 104E-10; 104E-20.*

**.0304 EXEMPT QUANTITIES: OTHER THAN SOURCE MATERIAL**

(a) Any person who possesses radioactive material received or acquired under the general license formerly provided in Rule .0303(b) of this Section is exempt from the requirements for a license set forth in this Section to the extent that such person possesses, uses, transfers or owns such radioactive material.

(b) This Rule does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(c) No person shall, for the purposes of commercial distribution, transfer individual quantities of radioactive materials to persons exempt from regulation in Paragraph (a) of this Rule except in accordance with a specific license issued by:

- (1) the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 for source and byproduct material;
- (2) the agency pursuant to Rule .0326 for radioactive material other than source, byproduct and special nuclear material; or
- (3) any agreement state pursuant to equivalent regulation for radioactive material other than source, byproduct and special nuclear material.

(d) Licensees for commercial distribution shall not transfer the quantities of radioactive material to persons exempt under Paragraph (e) of this Rule if the licensee knows or has reason to believe that the recipient will redistribute the quantities to persons exempt under Paragraph (e) of this Rule.

(e) Except as provided in Paragraphs (b) and (c) of this Rule, any person is exempt from the rules of this Chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in the following table:

**EXEMPT QUANTITIES**

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100

Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-71 (Ge 71)	100
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100



Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63( Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium -147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100

Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
<del>Sulphur</del> Sulfur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive	

material

0.1

Statutory Authority G.S. 104E-7; 104E-10(b); 104E-20.

**.0305 EXEMPT ITEM CONTAINING  
OTHER THAN SOURCE MATERIAL**

(a) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from the rules of this Chapter may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(b) Certain items containing radioactive material:

- (1) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from the rules of this Chapter to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:
  - (A) timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:
    - (i) 25 millicuries of tritium per timepiece;
    - (ii) five millicuries of tritium per hand;
    - (iii) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial);
    - (iv) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece;
    - (v) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand;
    - (vi) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);
    - (vii) the levels of radiation from hands

and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

- (I) for wrist watches, 0.1 millirad per hour at ten centimeters from any surface;
  - (II) for pocket watches, 0.1 millirad per hour at one centimeter from any surface;
  - (III) for any other timepiece, 0.2 millirad per hour at ten centimeters from any surface.
- (B) lock illuminators containing not more than 15 millicuries of tritium or not more than two millicuries of promethium-147 installed in automobile locks (the levels of radiation from each lock illuminator containing promethium-147 shall not exceed one millirad per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber);
  - (C) balances of precision containing not more than one millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part;
  - (D) automobile shift quadrants containing not more than 25 millicuries of tritium;
  - (E) marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas;
  - (F) thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat;
  - (G) electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material:
    - (i) 150 millicuries of tritium per microwave receiver protector tube or ten millicuries of tritium per any other electron tube;
    - (ii) one microcurie of cobalt-60;
    - (iii) five microcuries of nickel-63;
    - (iv) 30 microcuries of krypton-85;

- (v) five microcuries of cesium-137;
- (vi) 30 microcuries of promethium-147; and provided further, that the levels of radiation from each electron tube containing radioactive material does not exceed one millirad per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber (for purposes of this Subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents);
- (H) ionizing radiation measuring instruments containing for purposes of internal calibration or standardization, sources of radioactive material each not exceeding the applicable quantity set forth in Rule .0304(e) of this Section.
- (I) spark gap irradiation containing not more than one microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons (11.4 liters) per hour.
- (2) For purposes of Part (b)(1)(H) of this Rule, where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:
  - (A) Determine for each radionuclide in an ionizing radiation measuring instrument the ratio between the quantity present in the instrument and the exempt quantity established in Rule .0304(e) of this Section for the specific radionuclide when not in combination;
  - (B) No ratio shall exceed one and the sum of such ratios shall not exceed ten.
  - (C) For the purpose of ~~Subparagraph~~ Part (b)(1)(H) 0.05 microcurie of americium-241 is considered an exempt quantity under Rule .0304 of this Section.
- (c) Self-luminous products:
  - (1) Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from the rules of this Chapter to the extent that any person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.
  - (2) The exemption in Subparagraph (c)(1) of this Rule does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.
- (d) Gas and aerosol detectors:
  - (1) Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from the ~~regulations~~ rules of this Chapter to the extent that any person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall be manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or any agreement state, pursuant to Section 32.26 of 10 CFR 32, or equivalent, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.
  - (2) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under Subparagraph (d)(1) of this Rule, provided that the devices are labeled in accordance with the specific license authorizing distribution of the general licensed device, and providing further

that the devices meet the requirements of Rule .0327.

(e) Resins containing scandium-46:

- (1) Any person is exempt from these ~~Regulations~~ Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. These resins shall be manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall be manufactured in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.
- (2) This exemption does not authorize the manufacture of any resins containing scandium-46.

*Statutory Authority G.S. 104E-7; 104E-10(b); 104E-20.*

**.0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE**

(a) A license application for human use of radioactive material will be approved if the agency determines that:

- (1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these ~~Regulations~~ Rules;
- (2) The applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;
- (3) The issuance of the license will not be inimical to the health and safety of the public;
- (4) The following training and supervisory relationship are adhered to:
  - (A) the user of radioisotopes applied to humans for diagnostic, therapeutic, or investigational purposes shall be a physician authorized by a condition of a specific license, including a specific

license of broad scope.

(B) No authorized physician may delegate to persons who are not physicians under the supervision of the authorized physician, the following:

- (i) the approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources;
- (ii) the prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered;
- (iii) the determination of the route of administration;
- (iv) the interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered;

(5) the applicant satisfies any applicable special requirements in Rules .0319 to .0322 of this Section.

(b) Subject to the provisions of Subparagraph (a)(4) and Paragraphs (c) to (f) of this Rule, an authorized physician may permit technicians and other paramedic personnel to perform the following activities:

- (1) preparation and quality control testing of radiopharmaceuticals and sources of radiation;
- (2) measurement of radiopharmaceutical doses prior to administration;
- (3) use of appropriate instrumentation for the collection of data to be used by the physician;
- (4) administration of radiopharmaceuticals and radiation from radioisotope sources to patients.

(c) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to Paragraph (b) of this Rule shall:

- (1) prior to giving permission, determine that the technicians and other paramedical personnel have been properly trained to perform their duties with specific training in the following subjects, as applicable to the duties assigned:
  - (A) general characteristics of radiation and radioactive materials;
  - (B) physical, chemical, and pharmaceutical characteristics of each

radiopharmaceutical to be used;

- (C) mathematics and calculations basic to the use and measurement of radioactivity, including units of radiation dose and radiation exposure;
- (D) use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments;
- (E) principles and practices of radiation protection;
- (F) additional training in the above subjects, as appropriate, when new duties are added.

- (2) assure that the technicians and other paramedical personnel receive appropriate retraining in the subjects listed in Subparagraph (c)(1) of this Rule to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology;
- (3) keep records showing the bases for the determinations of proper training; and
- (4) retain responsibility as licensee or authorized user for the satisfactory performance of the activities.

(d) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medical technology by the Registry of Medical Technologists of the American Society of Clinical Pathologists or the Society of Nuclear Medicine will be deemed to satisfy the training requirements in Subparagraphs (c)(1) and (2) of this Rule.

(e) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to Paragraph (b) of this Rule and, if so, shall include in his application for license, license amendment, or license renewal a statement of the activities to be so performed and a description of an adequate program for training the personnel, including retraining as required to keep abreast of developments in technology, or for otherwise determining that the personnel are properly trained to perform their duties.

(f) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician shall be immediately accessible, but not necessarily a physician authorized by the agency to be a user of radioisotopes.

Statutory Authority G.S. 104E-7; 104E-10(b).

### **.0321 SPECIFIC LICENSES: GROUPS OF DIAGNOSTIC USES**

(a) An application for a specific license pursuant to Rule .0318 of this Section for any diagnostic or therapeutic use of radioactive material specified in groups established in Paragraph (b) of this Rule will be approved for all of the diagnostic or therapeutic uses within the group which include the use specified in the application if:

- (1) the applicant satisfies the requirements in Rule .0319 of this Section;
- (2) the applicant's proposed radiation detection instrumentation is adequate for conducting the diagnostic or therapeutic procedure specified in the appropriate group;
- (3) the physicians designated in the application as individual users, have adequate clinical experience in the types of uses included in the group or groups;
- (4) the physicians and all other personnel who will be involved in the preparation and use of radioactive material have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;
- (5) the applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.

(b) The groups of diagnostic and therapeutic radiopharmaceutical uses are established as follows:

- (1) Group I includes radiopharmaceuticals for which a New Drug application has been approved by the U.S. Food and Drug Administration for diagnostic studies involving measurement of uptake, dilution and excretion. This group does not include the use of any radiopharmaceutical disapproved by the North Carolina Radiation Protection Commission or involving imaging, tumor localization or therapy.
- (2) Group II includes radiopharmaceuticals for which a New Drug application has been approved by the U.S. Food and Drug Administration for diagnostic studies involving imaging and tumor localizations. This group does not include the use of any

radiopharmaceutical disapproved by the North Carolina Radiation Protection Commission.

- (3) Group III includes the use of generators and reagent kits for which a New Drug application has been approved by the U.S. Food and Drug Administration for the preparation of radiopharmaceuticals for certain diagnostic uses. This group does not include any generator or reagent kit disapproved by the North Carolina Radiation Protection Commission.
- (4) Group IV includes radiopharmaceuticals for which a New Drug application has been approved by the U.S. Food and Drug Administration for therapeutic uses which do not normally require hospitalization for purposes of radiation safety. This group does not include any radiopharmaceutical disapproved by the North Carolina Radiation Protection Commission.

(c) Any licensee who is authorized to use radioactive material in one or more groups pursuant to Paragraph (a) of this Rule is subject to the following conditions:

- (1) For Groups I, II and IV, no licensee shall receive, possess, or use radioactive materials except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged, and distributed in accordance with:
  - (A) a specific license issued by the U.S. Nuclear Regulatory Commission, pursuant to Section 32.72 of 10 CFR Part 32; or
  - (B) a specific license issued by the agency or an agreement state pursuant to equivalent regulations.
- (2) For Group III, no licensee shall receive, possess, or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:
  - (A) reagent kits, not containing radioactive material, that are approved by the U.S. Nuclear Regulatory Commission, the U.S. Atomic Energy Commission, or an agreement state for use by persons licensed for Group III pursuant to

Paragraph (a) of this Rule or equivalent regulations of an agreement state or the U.S. Nuclear Regulatory Commission;

- (B) generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.73 of 10 CFR Part 32 or by the agency or an agreement state pursuant to equivalent regulations;
- (C) any licensee who uses generators or reagent kits shall elute the generator or process radioactive material with the reagent kit in accordance with instructions which are approved by the U.S. Nuclear Regulatory Commission or an agreement state and are furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.
- (3) For Groups I, II and III, any licensee using radioactive material for clinical procedures other than those specified in the product labeling package insert shall comply with the product labeling regarding:
  - (A) chemical and physical form;
  - (B) route of administration; and
  - (C) dosage range.
- (4) Any licensee who is licensed pursuant to Paragraph (a) of this Rule for one or more of the medical use groups also is authorized to use radioactive material under the general license in Rule .0314 of this Section for the specified IN VITRO uses without filing agency form as required by Rule .0314(b) of this Section, provided that the licensee is subject to the other provisions of Rule .0314 of this Section.
- (5) Any licensee who is licensed pursuant to Paragraph (a) of this Rule for one or more of the medical use groups in Paragraph (a) of this Rule also is authorized, subject to the provisions of ~~Subparagraphs~~ Parts (c)(5)(E) and (F) of this Rule, to receive, possess, and use for calibration and reference standards:
  - (A) Any radioactive material listed in

- Group I, Group II, or Group III of this Rule with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries total;
- (B) Any radioactive material listed in Group I, Group II, or Group III of this Rule with half-life greater than 100 days in amounts not to exceed 200 microcuries total;
- (C) Technetium-99m in amounts not to exceed 30 millicuries;
- (D) Any radioactive material in amounts not to exceed three millicuries per source contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with:
- (i) a specific license issued to the manufacturer by an agreement state pursuant to equivalent state regulations;
  - (ii) a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR, Part 32; or
  - (iii) an application filed with the U.S. Atomic Energy Commission pursuant to Section 32.74 of 10 CFR, part 32; or
  - (iv) an application filed with an agreement state pursuant to equivalent state regulations on or before October 15, 1974 for a license to manufacture a source that the applicant distributed commercially on or before August 16, 1974, on which application the U.S. Atomic Energy Commission or the U.S. Nuclear Regulatory Commission or the agreement state has not acted.
- (E) Any licensee who possesses sealed sources as calibration or reference sources pursuant to Subparagraph (c)(5) of this Rule shall cause each sealed source containing radioactive material other than hydrogen-3 with a half-life greater than 30 days in any form other than gas to be tested for leakage or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed source shall not be used until tested. No leak tests are required when:
- (i) The source contains 100 microcuries or less of beta or gamma emitting material or ten microcuries or less of alpha emitting material.
  - (ii) The sealed source is stored and is not being used.
- Such source shall be tested for leakage prior to any use or transfer unless they have been leak tested within six months prior to the date of use or transfer.
- (F) The leak test shall be capable of detecting the presence of 0.005 microcuries of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the agency.
- (G) If the leak test reveals the presence of 0.005 microcuries or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with agency regulations. A report shall be filed within five days of the test with the agency address in Rule .0111 of this Chapter describing the equipment involved, the test results, and the corrective action taken.
- (H) Any licensee who possesses and uses calibration and reference sources pursuant to Subparagraph (c)(5) of this Rule shall:
- (i) follow the radiation safety and handling instructions approved by the agency or an agreement state and furnished by the manufacturer on the label attached to the source or permanent container thereof or in the leaflet or brochure that accompanies the source;
  - (ii) maintain such instructions in a legible and conveniently available form;



- (iii) conduct a quarterly physical inventory to account for all sources received and possessed; Records of the inventories shall be maintained for inspection by the agency and shall include the quantities and kinds of radioactive material, location of sources and the date of the inventory.

(d) Current lists of the radiopharmaceuticals, generators, reagent kits, and associated uses in Group I to IV are available from the agency at the address in Rule .0111 of this Chapter.

*Statutory Authority G.S. 104E-7; 104E-10(b).*

#### **.0324 SPECIFIC LICENSES: BROAD SCOPE**

(a) In addition to the requirements set forth in Rule .0317 of this Section, a specific license of broad scope for radioactive material will be issued if:

- (1) the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and
- (2) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:
  - (A) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;
  - (B) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety measures; and
  - (C) the establishment of appropriate administrative procedures to assure:
    - (i) control of procurement and use of radioactive material;
    - (ii) completion of safety evaluations of proposed ~~used~~ uses of radioactive material which ~~taken~~ takes into consideration such matters as the adequacy of facilities and equipment, training

and experience of the user, and the operating or handling procedures; and

- (iii) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with ~~Subparagraph~~ Part (a)(2)(C) of this Rule prior to use of the radioactive material.

(3) Unless specifically authorized pursuant to other ~~Rules~~ rules of this Section, persons licensed under this Rule shall not:

- (A) conduct tracer studies in the environment involving direct release of radioactive material;
- (B) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies or more of byproduct material in sealed sources used for irradiation of materials;
- (C) conduct activities for which a specific license issued by the agency under ~~.0300~~ the rules of this Section is required; or
- (D) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(4) Each specific license of broad scope issued under this Rule shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(b) In addition to the requirements set forth in Rule .0319 of this Section, a specific license of broad scope for radioactive material, human use, will be issued only if:

- (1) the applicant has appointed a radiation safety committee as required in ~~Subparagraph~~ Part (a)(2)(A) of this Rule, except that this committee shall evaluate all proposals for research, diagnostic and therapeutic use of radioactive material within the medical facility;
- (2) membership of the committee consists of physicians specializing in nuclear medicine, diagnostic radiology, clinical

- pathology, and a pharmacist specializing in radiopharmacy, someone competent in radiation safety and a representative of the hospital management; and
- (3) the applicant for a medical radioactive materials license of broad scope has an ongoing teaching program with interns and residents associated with a four-year medical school.

*Statutory Authority G.S. 104E-7; 104E-10(b).*

**.0325 SPECIFIC LICENSES: PRODUCTS WITH EXEMPT CONCENTRATIONS**

(a) In addition to the requirements set forth in Rule .0317 of this Section, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under Rule .0303(b) of this Section will be issued if:

- (1) the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and
- (2) the applicant provides reasonable assurance that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being, use of lower concentration is not feasible and that the concentrations of radioactive material at the time of transfer, or that reconcentration of the radioactive material, will not exceed the concentrations listed in the table in Rule .0303(b) of this Section.

- (A) Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in the

table in Rule .0303(b) of this Section, the activity stated is that of the parent isotope and takes into account the daughters.

- (B) Values are given in Column I of the table in Rule .0303(b) of this Section, only for those materials normally used as gases.
- (C) For purposes of this Rule where there is involved a combination of isotopes, the limit for the combination shall be derived as follows:
- (i) Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in the table in Rule .0303(b) of this Section for the specific isotope when not in combination.
- (ii) The sum of these ratios shall not exceed unity.

Example:

Concentration of Isotope A in Product

Exempt concentration of Isotope A +

Concentration of Isotope B in Product

Exempt concentration of Isotope B less than or equal to 1

(b) Each person licensed under Paragraph (a) of this Rule shall file with the agency an annual report which shall identify:

- (1) the type and quantity of each product or material into which radioactive material has been introduced during the reporting period;
- (2) name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction;
- (3) the type and quantity of radionuclide introduced into each such product or material; and
- (4) the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

If no transfers of radioactive material have been made pursuant to Paragraph (a) of this Rule during the reporting period, the report shall so indicate. The report shall cover the 12-month period ending June 30, and shall be filed within 30 days thereof.

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Statutory Authority G.S. 104E-7; 104E-10(b).

### **.0326 SPECIFIC LICENSES: EXEMPT DISTRIBUTION**

(a) An application for a specific license to distribute radioactive material other than source, byproduct or special nuclear material to persons exempt from these ~~Regulations~~ Rules pursuant to Rule .0304(e) of this Section will be approved if:

- (1) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;
- (2) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and
- (3) The applicant submits copies of prototype labels and brochures and the agency approves their labels and brochures.

(b) The license issued pursuant to this Rule is subject to the following conditions:

- (1) No more than ten exempt quantities shall be sold or transferred in any single transaction. An exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fraction shall not exceed unity.
- (2) Each exempt quantity shall be separately and individually packaged. No more than ten packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Rule .0304(e) of this Section. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.
- (3) The immediate container of each quantity of separately packaged fractional quantity of radioactive material shall bear the words "Radioactive Material".
- (4) In addition to the labeling information required by Subparagraph (b)(3) of this

Rule, the label affixed to the immediate container, or an accompanying brochure, shall:

- (A) state that the contents are exempt from U.S. Nuclear Regulatory Commission or agreement state requirements;
- (B) contain the following statements:
  - (i) Radioactive material;
  - (ii) Not for human use;
  - (iii) Introduction into foods, beverages, cosmetics, drugs, or medicinals, or into products manufactured for commercial distribution is prohibited;
  - (iv) Exempt quantities should not be combined.
- (C) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(c) Each person licensed under Paragraph (a) of this Rule shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under Rule .0304(e) of this Section or the equivalent regulations of an agreement state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the agency. Each report shall cover the 12 month period ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to this Rule during the reporting period, the report shall so indicate.

(d) Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Statutory Authority G.S. 104E-7; 104E-10(b).

### **.0336 COPIES OF APPLICABLE FEDERAL REGULATIONS**

~~Copies of the applicable regulation from Title 10 of the Code of Federal Regulations (10 CFR) referenced in Rules .0321, .0327, .0329, .0330,~~

~~.0332, .0333, .0334, .0335, .0336, and .0337 of this Section are available from the agency at the address in Rule .0111 of this Chapter.~~

*Statutory Authority G.S. 104E-7; 104E-10(b).*

### **.0337 ISSUANCE OF SPECIFIC LICENSES**

(a) Upon a determination that an application meets the requirements of the Act and the ~~Regulations~~ rules of this Section, the agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The agency may incorporate in any license at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this Chapter as it deems appropriate or necessary in order to:

- (1) minimize danger to public health and safety or property;
- (2) require such reports and the keeping of such records, and provide for such inspections of activities under the license as may be appropriate or necessary; and
- (3) prevent loss or theft of radioactive material subject to this Section.

*Statutory Authority G.S. 104E-7; 104E-10(b).*

### **.0338 SPECIFIC TERMS AND CONDITIONS OF LICENSES**

(a) Each license issued pursuant to ~~this part the rules in this Section~~ shall be subject to all the provisions of the Act, now or hereafter in effect, to all rules and regulations adopted pursuant to provisions of the Act and to orders of the agency.

(b) No license issued or granted pursuant to this Section and no right to possess or utilize radioactive material granted by any license issued pursuant to this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency, after securing full information, finds that the transfer is in accordance with the provisions of the Act, and gives its consent in writing.

(c) Each person licensed by the agency pursuant to this Section shall confine his use and possession of the radioactive material licensed to the locations and purposes authorized in the license.

(d) Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

- (1) licensee;
- (2) an entity [as that term is defined in 11 U.S.C. 101(14)] controlling the licensee or listing the license or licensee as property of the estate; or
- (3) an affiliate [as that term is defined in 11 ~~U.S.C.~~ U.S.C. 101(2)] of the licensee.

(e) The notification in Paragraph (d) of this Rule shall indicate:

- (1) the bankruptcy court in which the petition for bankruptcy was filed; and
- (2) the date of the filing of the petition.

(f) Licensees required to submit emergency plans pursuant to Rule .0352 of this Section shall follow the emergency plan approved by the agency. The licensees may change the approved plan without agency approval only if the licensee believes the changes do not decrease the effectiveness of the plan and are submitted to the agency no later than 20 calendar days after the changes are made. The licensee shall furnish the change to affected off-site response organizations within six months after the change is made. Proposed changes that the licensee believes are likely to decrease, or may potentially decrease, the effectiveness of the approved emergency plan shall not be implemented without prior application to and prior approval by the agency.

*Statutory Authority G.S. 104E-7; 104E-10(b).*

### **.0343 TRANSFER OF MATERIAL**

(a) No licensee shall transfer radioactive material except as authorized pursuant to this Section.

(b) Except as otherwise provided in his license and subject to the provisions of Paragraphs (c), (d) and (e) of this Rule any licensee may transfer radioactive material to:

- (1) the agency;
- (2) the U.S. Department of Energy;
- (3) any person exempt from the ~~Regulations~~ rules in this Section to the extent permitted under the exemption;
- (4) any person authorized to receive the radioactive material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the U.S. Nuclear Regulatory Commission.

or an agreement state, or any person otherwise authorized to receive the radioactive material by the federal government or any agency thereof, the agency, or an agreement state; or

- (5) as otherwise authorized by the agency in writing.

(c) A licensee may transfer material to the agency only after receiving prior approval from the agency.

(d) Before transferring radioactive material to a specific licensee of the agency, the U.S. Nuclear Regulatory Commission, or an agreement state, or to a general licensee who is required to register with the agency, the U.S. Nuclear Regulatory Commission, or an agreement state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(e) The following methods for the verification required by Paragraph (d) of this Rule are acceptable:

- (1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;
- (2) The transferor may have in his possession a written certificate by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;
- (3) For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided the oral certification is confirmed in writing within ten days after the date of the oral certification;
- (4) The transferor may obtain other sources of information compiled by a reporting service from official records of the agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an agreement state as to the identity of

licensees and the scope and expiration dates of licenses and registration; or

- (5) When none of the methods of verification described in this Rule are readily available or when a transferor desires to verify that information received by one of the methods is correct or updated, the transferor may obtain and record confirmation from the agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an agreement state that the transferee is licensed to receive the radioactive material.

(f) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Rule .0346 of this Section.

*Statutory Authority G.S. 104E-7; 104E-10(b).*

#### **.0344 MODIFICATION: REVOCATION: AND TERMINATION OF LICENSES**

(a) The terms and conditions of all licenses are subject to amendment, revision or modification and all licenses are subject to suspension or revocation by reason of:

- (1) amendments to the Act,
- (2) rules and regulations adopted pursuant to provisions of the Act, or
- (3) orders issued by the agency pursuant to provisions of the Act and rules and regulations adopted pursuant to provisions of the Act.

(b) Any license may be revoked, suspended, or modified, in whole or in part:

- (1) for any material false statement in the application or in any statement of fact required by provisions of this Section;
- (2) because of conditions revealed by:
  - (A) the application;
  - (B) any statement of fact;
  - (C) any report, record, inspection or other means, which would warrant the agency to refuse to grant a license or an original application; or
- (3) for violation of, or failure to observe any of the terms and conditions of the Act, the license, the ~~Rules~~ rules of this Chapter, or order of the agency.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for modification, revocation, or suspension of a license, the agency shall:

- (1) call to the attention of the licensee in

writing the facts or conduct which may warrant these actions, and

- (2) provide an opportunity for the licensee to demonstrate or achieve compliance with all lawful requirements.

(d) The agency may terminate a specific license upon request submitted by the licensee to the agency in writing.

*Statutory Authority G.S. 104E-7; 104E-10(b).*

#### **.0345 RECIPROCAL RECOGNITION OF LICENSES**

(a) Subject to these ~~Regulations~~ Rules, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that the following requirements are satisfied:

- (1) The licensing document does not limit the activity authorized by such document to specified installations or locations;
- (2) The out-of-state licensee notifies the agency in writing at least three days prior to engaging in such activity: such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document; if, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, he may upon application to the agency, obtain permission to proceed sooner; the agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this Rule;
- (3) The out-of-state licensee complies with all applicable regulations of the agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations

of the agency;

- (4) The out-of-state licensee supplies such other information as the agency may request; and

- (5) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this Rule except by transfer to a person:

(A) specifically licensed by the agency or by the U.S. Nuclear Regulatory Commission to receive the material, or

(B) exempt from the requirements for a license for the material under Rule .0303 of this Section.

(b) Additional reciprocity is provided in Rule .0310 of this Section.

(c) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that the action is necessary in order to prevent undue hazard to public health and safety or property.

*Statutory Authority G.S. 104E-7; 104E-10(b).*

#### **.0346 PREPARATION OF RADIOACTIVE MATERIAL FOR TRANSPORT**

(a) No licensee shall deliver any radioactive material to a carrier for transport, unless:

- (1) The licensee complies with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the packing of radioactive material, and to the monitoring, marking and labeling of those packages;

(2) The licensee has established procedures for opening and closing packages in which radioactive material is transported to provide safety and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and

(3) Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to, or have been available to the consignee.

(b) For the purpose of this Rule, a licensee who

transports his own licensed material as a private carrier is considered to have delivered the material to a carrier for transport.

(c) In addition to the requirements of Paragraphs (a) and (b) of this Rule, prior to the transport of any nuclear waste, as defined in Part (d)(2)(A) of Rule .0316(d)(2)(A) of this Section, outside the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor's designee of each state through which the waste will be transported.

(d) Each advance notification required by Paragraph (c) of this Rule shall contain the following information:

- (1) the name, address, and telephone number of the shipper, carrier and receiver of the shipment;
- (2) a description of the nuclear waste contained in the shipment as required by the regulations of the U.S. Department of Transportation in 49 CFR 172.202 and 172.203(d);
- (3) the point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;
- (4) the seven-day period during which arrival of the shipment at state boundaries is estimated to occur;
- (5) the destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and
- (6) a point of contact with a telephone number for current shipment information.

(e) The notification required by Paragraph (c) of this Rule shall be made in writing to the office of each appropriate governor or governor's designee. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor or governor's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for one year.

(f) The licensee shall notify each appropriate governor or governor's designee of any changes to schedule information provided pursuant to

Paragraph (c) of this Rule. Such notification shall be by telephone to a responsible individual in the office of the governor or governor's designee of the appropriate state or states. The licensee shall maintain for one year a record of the name of the individual contacted.

(g) Each licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor or governor's designee of the appropriate state or states. A copy of the notice shall be retained by the licensee for one year.

(h) A list of governors or governors' designees for other states is available from the agency by contacting the North Carolina Division of Radiation Protection, P.O. Box 27687, Raleigh, North Carolina 27611-7687, Phone No. 919/733-4283 571-4141 or facsimile number 919/571-4148. For the notification required in Paragraphs (c) through (g) of this Rule in North Carolina:

- (1) governor's designee is the North Carolina Highway Patrol, Operations Office;
- (2) mailing address: P. O. Box 27687, Raleigh, North Carolina 27611-7687;
- (3) telephone 919/733-4030 from 8 a.m. to 5 p.m. workdays, and 919/733-3861 all other times.

*Statutory Authority G.S. 104E-7; 104E-10(b); 104E-15(a).*

**.0352 EMERGENCY PLANS**

- (a) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in the table in Subparagraph (e)(1) of this Rule must contain either:
- (1) an evaluation showing that the maximum dose to a person off-site due to a release of radioactive materials would not exceed one rem effective dose equivalent or five rems to the thyroid; or
  - (2) an emergency plan for responding to a release of radioactive material.
- (b) One or more of the following factors may be used to support an evaluation submitted under Subparagraph (a)(1) of this Rule:
- (1) the radioactive material is physically separated so that only a portion could be involved in an accident;
  - (2) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
  - (3) the release fraction in the respirable size range would be lower than the release fraction shown in Subparagraph (e)(1) of this Rule due to the chemical or physical form of the material;
  - (4) the solubility of the radioactive material would reduce the dose received;
  - (5) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Subparagraph (e)(1) of this Rule;
  - (6) operating restrictions or procedures would prevent a release fraction as large as that shown in Subparagraph (e)(1) of this Rule; or
  - (7) other factors appropriate for the specific facility.
- (c) An emergency plan for responding to a release of radioactive material submitted under Subparagraph (a)(2) of this Rule must include the following information:
- (1) brief description of the licensee's facility and area near the site;
  - (2) identification of each type of radioactive materials accident for which protective actions may be needed;
  - (3) classification system for classifying accidents as alerts or site area emergencies;
  - (4) identification of the means of detecting each type of accident in a timely manner;
  - (5) brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining the equipment;
  - (6) brief description of the methods and equipment to assess releases of radioactive materials;
  - (7) brief description of the responsibilities of licensee personnel, should an accident occur, including identification of personnel responsible for promptly notifying off-site response organizations and the agency, and responsibilities for developing, maintaining, and updating the plan;
  - (8) brief description of notification and coordination, to include a commitment to and a brief description of the means to promptly notify off-site response organizations and request off-site assistance, including medical assistance for the treatment of contaminated injured on-site workers when appropriate, provided that:
    - (A) a control point shall be established;
    - (B) the notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination;
    - (C) the licensee shall also commit to notify the agency immediately after notification of the appropriate off-site response organizations, not to exceed one hour after the licensee declares an emergency; and
    - (D) the reporting requirements in Subparagraph (c)(8) of this Rule do not substitute for or relieve the licensee from responsibility for complying with the requirements in the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 or other state or federal reporting requirements;
  - (9) brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the agency;
  - (10) brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency, including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel, where such training shall:



- (A) familiarize personnel with site-specific emergency procedures; and
- (B) thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios;
- (11) brief description of the means of restoring the facility to a safe condition after an accident;
- (12) brief description of provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies where such provisions shall meet the following specific requirements:
  - (A) quarterly communications checks with off-site response organizations shall include the check and update of all necessary telephone numbers;
  - (B) while participation of off-site response organizations in biennial exercises is encouraged but not required, the licensee shall invite off-site response organizations to participate in the biennial exercises;
  - (C) accident scenarios for biennial exercises shall not be known to most exercise participants;
  - (D) the licensee shall critique each exercise using individuals who do not have direct implementation responsibility for the plan; and
  - (E) critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response; and
  - (F) deficiencies found by the critiques in Subparagraph Part (c)(12)(E) of this Rule shall be corrected;
- (13) certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(d) The licensee shall allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. The licensee shall provide any comments received within the 60 day comment period to the agency with the emergency plan.

(e) Quantities of radioactive material requiring consideration of the need for an emergency plan for responding to a release as used in this Rule and special instructions for use are:

(1) TABLE

RADIOACTIVE MATERIAL	RELEASE FRACTION	QUANTITY (CURIES)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14 (NON CO)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000

Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166 m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114 m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110 m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99 m	.01	400,000
Tellurium-127 m	.01	5,000
Tellurium-129 m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000

Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha	.0001	20

- (2) For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in the table in Subparagraph (e)(1) of this Rule exceeds one.
- (3) Waste packaged in Type B containers, as defined in 10 CFR Part 71.4, does not require an emergency plan.

*Statutory Authority G.S. 104E-7; 104E-18.*

## **SECTION .0500 - SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY OPERATIONS**

### **.0501 PURPOSE AND SCOPE**

(a) The ~~regulations~~ rules in this Section establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography. The requirements of this Section are in addition to and not in substitution for the other requirements of this Chapter.

(b) The ~~regulations~~ rules in this Section apply to all licensees or registrants who use sources of radiation for industrial radiography; provided, however that nothing in this Section shall apply to the use of sources of radiation in the healing arts.

*Statutory Authority G.S. 104E-7.*

### **.0507 LEAK TESTING AND SOURCE TAGGING**

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons specifically authorized by the agency to do so.

(b) Each sealed source shall be tested for leakage at intervals not to exceed six months. In the absence of a certificate from a transferor that a test has been made within the six months prior to the transfer, the sealed source shall not be put into use until tested.

(c) The leak test shall be capable of detecting the presence of 0.005 microcurie of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to Rule .0323(5) of this Chapter. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the agency for six months after the next required leak test is performed or until the sealed source is disposed of or transferred.

(d) Any test conducted pursuant to Paragraphs (b) and (c) of this Rule which reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of,

in accordance with these ~~Regulations~~ Rules. A report describing the equipment involved, the test results, and the corrective action taken shall be submitted in writing to the agency at the address in Rule .0111 of this Chapter within five days after the test.

(e) A sealed source which is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag at least one inch square bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions "Danger - Radioactive Material. Do Not Handle. Notify Civil Authorities If Found."

*Statutory Authority G.S. 104E-7.*

#### **.0510 LIMITATIONS**

(a) The licensee or registrant shall not permit any person to act as a radiographer until the person:

- (1) has been instructed in the subjects outlined in Rule .0518 of this Section and has demonstrated understanding thereof;
- (2) has received copies of and instruction in the ~~Rules~~ rules contained in this Section and in the applicable rules of Section .0300 and .0900 of this Chapter, and the licensee's or registrant's operating and emergency procedures, and has demonstrated understanding thereof;
- (3) has demonstrated competence to use the radiographic exposure devices, sealed sources, related handling tools and survey instruments which will be employed in his assignment; and
- (4) has demonstrated understanding of the instructions in Paragraph (a) of this Rule by successful completion of a written test and a field examination on the subjects covered.

(b) The licensee or registrant shall not permit any person to act as a radiographer's assistant until the person:

- (1) has received copies of and instructions in the licensee's or registrant's operating and emergency procedures, and has demonstrated understanding thereof;
- (2) has demonstrated competence to use under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, related

handling tools and radiation survey instruments which will be employed in his assignment; and

- (3) has demonstrated understanding of the instructions in Paragraph (b) of this Rule by successfully completing a written or oral test and a field examination on the subjects covered.

(c) Records of the training including copies of written tests and dates of oral tests and field examinations shall be maintained for three years.

(d) Each licensee or registrant shall conduct an internal audit program to ensure that the agency's radioactive material license, registration conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer and radiographer's assistant. These internal audits shall be performed and records maintained as specified in ~~Subparagraphs~~ Sub-items (3)(a) and (b) of Rule .0323 of this Chapter.

*Statutory Authority G.S. 104E-7.*

#### **.0518 RADIATION MACHINES**

The following are special requirements for radiography employing radiation machines:

- (1) Cabinet radiography using radiation machines, as defined in Rule .0502~~(f)~~ of this Section shall be exempt from requirements of this Section; except that no registrant shall permit any individual to operate a cabinet radiography unit until the individual has received a copy of, and instruction in, and demonstrated an understanding of operating procedures for the unit, and has demonstrated competence in its use.
- (2) Shielded Room Radiography using radiation machines, as defined in Rule .0502~~(g)~~ of this Section, shall be exempt from the requirements of this Section; except that:
  - (a) No registrant shall permit any individual to operate a radiation machine for shielded room radiography until the individual has received a copy of, and instruction in, and demonstrated an understanding of operating procedures for the unit, and has demonstrated competence in its use.
  - (b) Each registrant shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by, every individual who operates, who makes "set-ups" or who performs

maintenance on a radiation machine for shielded room radiography.

- (c) A physical radiation survey shall be conducted to determine that the radiation machine is "off" prior to each entry into the shielded room. Such surveys shall be made with a radiation measuring instrument which is capable of measuring radiation of the energies and at the exposure rates to be encountered, which is in good working order, and which has been properly calibrated within the preceding three months or following the last instrument servicing, whichever is later.
- (3) Other radiography using radiation machines are exempt from Rules .0503, .0505, .0507, and .0508 of this Section; however:
  - (a) A physical radiation survey shall be conducted to determine that the radiation machine is "off" prior to each entry into the radiographic exposure area. Such surveys shall be made with a radiation measuring instrument capable of measuring radiation of the energies and at the exposure rates to be encountered, which is in good working order, and which has been properly calibrated within the preceding three months or following the last instrument servicing, whichever is later. Survey results and records of boundary locations shall be maintained and kept available for inspection; and
  - (b) Mobile or portable radiation machines shall be physically secured to prevent removal by unauthorized personnel.

*Statutory Authority G.S. 104E-7; 104E-12(a)(1).*

## **SECTION .0600 - X-RAYS IN THE HEALING ARTS**

### **.0602 DEFINITIONS**

(a) As used in this Section, the following definitions shall apply:

- (1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
- (2) "Added filter" means the filter added to the inherent filtration.
- (3) "Aluminum equivalent" means the thickness of aluminum, type 1100 alloy, affording the same attenuation, under

specified conditions, as the material in question. The nominal composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum and 0.12 percent copper.

- (4) "Attenuation block" means a block or stack, having dimensions 20 cm by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.
- (5) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation. Phototimer is described separately.
- (6) "Beam axis" means a line from the source of x-rays through the centers of the x-ray fields.
- (7) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.
- (8) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
- (9) "Changeable filters" means any added filter which can be removed from the useful x-ray beam through any electronic, mechanical or physical process.
- (10) "Contact therapy system" means that the x-ray tube target is put within five centimeters of the surface being treated.
- (11) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.
- (12) "Cooling curve" means the graphical relationship between heat units stored and cooling time.
- (13) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
- (14) "Diagnostic source assembly" means the tube housing assembly with a device attached.
- (15) "Diagnostic-type protective tube housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 mR in one hour when the tube is

- operated at its leakage technique factors.
- (16) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.
- (17) "Direct scattered radiation" means that radiation which has been deviated in direction by materials irradiated by the useful beam. (See also scattered radiation).
- (18) "Entrance exposure rate" means the roentgens per unit time at the point where the center of the useful beam enters the patient.
- (19) "Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons, negatrons and positrons, liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The special unit of exposure is the roentgen.
- (20) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.
- (21) "Filter" means material placed in the useful beam to preferentially attenuate selected radiations.
- (22) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks and structural material providing linkage between the image receptor and the diagnostic source assembly.
- (23) "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.
- (24) "Gonad shield" means a protective barrier used to reduce exposure to the testes or ovaries.
- (25) "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
- (26) "Healing arts mass screening" means the examination of human beings using x-rays for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts who is legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment. It does not include the use of x-ray tests as a requirement for hospital admission or as a condition of employment.
- (27) "Image intensifier" means a device, including housing, which converts an x-ray pattern into a corresponding light image of higher energy density.
- (28) "Image receptor" means any device, such as fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.
- (29) "Inherent filtration" means the filtration permanently in the useful beam; it includes the window of the x-ray tube and any permanent tube or source enclosure.
- (30) "Installation" means the act of physical movement of a radiographic system from one location to another in conjunction with a change of ownership.
- (31) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.
- (32) "Leakage radiation" means radiation emanating from a diagnostic or therapeutic source assembly except for:
  - (A) the useful beam and
  - (B) radiation produced when the exposure switch or timer is not activated.
- (33) "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly (i.e., tube housing and beam limiting device) which are used in measuring leakage radiation. They are defined as follows:
  - (A) for diagnostic source assemblies

- intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mC) or the minimum obtainable from the unit, whichever is larger;
- (B) for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated peak tube potential and the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential; and
- (C) for all other diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube potential.
- (34) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.
- (35) "Maximum line current" means the rms (root-mean-square) current in the supply line of an x-ray machine operating at its maximum rating.
- (36) "Mobile equipment" (see x-ray equipment).
- (37) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
- (38) "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see also "Automatic exposure control").
- (39) "Portable equipment" (see x-ray equipment).
- (40) "Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-skin distance. It may or may not incorporate or serve as a beam-limiting device.
- (41) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for radiation protection purposes, to reduce the radiation exposure.
- (42) "Protective apron" means an apron made of radiation attenuating materials used to reduce radiation exposure.
- (43) "Protective barrier" means a barrier of radiation attenuating material(s) used to reduce radiation exposure. Types of protective barriers are defined in Rules other Items of this Rule. .0602(41) and .0602(53).
- (44) "Protective glove" means a glove made of radiation attenuating materials used to reduce radiation exposure.
- (45) "Qualified expert" means an individual who has demonstrated to the satisfaction of the agency that he possesses the knowledge and training to measure ionizing radiation parameters, to evaluate safety techniques and to advise regarding radiation protection needs and who is registered pursuant to Rule .0205 of this Chapter.
- (46) "Radiograph" means an image receptor on which the image has been created directly or indirectly by an x-ray pattern and results in a permanent record.
- (47) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.
- (48) "Rating" means the operating limits as specified by the component manufacturer.
- (49) "Recording" means producing a permanent form of an image resulting from x-ray photons such as film and video tape.
- (50) "Registrant", as used in this Section, means any person who owns or possesses and administratively controls an x-ray system which is used to deliberately expose humans or animals to the useful beam of the system and is required by the provisions contained in Sections .0100 and .0200 of this

- Chapter to register with the agency.
- (51) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state mid-scale reading.
  - (52) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. (See also "direct scattered radiation".)
  - (53) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.
  - (54) "SID" means source-image receptor distance.
  - (55) "Source" means the focal spot of the x-ray tube.
  - (56) "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.
  - (57) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
  - (58) "Stationary equipment" (see x-ray equipment).
  - (59) "Stray radiation" means the sum of leakage and scattered radiation.
  - (60) "Technique factors" means the conditions of operation. They are specified as follows:
    - (A) for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
    - (B) for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and
    - (C) for all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.
  - (61) "Therapeutic-type protective tube housing" means the tube housing with tube installed, and it includes high voltage and filament transformers and other appropriate elements when they are contained within that housing.
  - (62) "Transportation equipment" means x-ray equipment which is installed in a vehicle or trailer.
  - (63) "Tube" means an x-ray tube, unless otherwise specified.
  - (64) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and filament transformers and other appropriate elements when they are contained within the tube housing.
  - (65) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
  - (66) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.
  - (67) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at the given SID.
  - (68) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.
  - (69) "X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices which control the technique factors of an x-ray exposure.
  - (70) "X-ray equipment" means an x-ray system, subsystem or component thereof.
    - (A) "Mobile equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.
    - (B) "Portable equipment" means x-ray equipment designed to be hand-carried.
    - (C) "Stationary equipment" means x-ray equipment which is installed in a fixed location.
  - (71) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is



one-fourth of the maximum in the intersection.

- (72) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.
- (73) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.
- (74) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this Section.
- (75) "X-ray tube" means an electron tube which is designed for the conversion of electrical energy into x-ray energy.

(b) Other definitions applicable to this Section may be found in Sections .0100 and .0200 of this Chapter.

*Statutory Authority G.S. 104E-7.*

#### **.0605 FLUOROSCOPIC X-RAY SYSTEMS**

All fluoroscopic x-ray systems shall meet the following requirements:

- (1) Limitation of useful beam
  - (a) The fluoroscopic tube shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam at all times.
  - (b) The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID.
- (c) Limitation to the Imaging Surface
  - (i) The x-ray field produced by fluoroscopic equipment without image intensification shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic

procedures and spot-filming procedures.

- (ii) Image-intensified fluoroscopy and spot-filming shall comply with the following:
  - (A) During fluoroscopic or spot-filming procedures, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID.
  - (B) Compliance shall be determined with the beam axis perpendicular to the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.
- (iii) In addition to other requirements of this Rule, equipment manufactured after the effective date of these Rules shall comply with the following:
  - (A) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. This adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film.
  - (B) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID, shall be equal to or less than five centimeters by five centimeters.
  - (C) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID.

- (2) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.
- (3) Entrance exposure rates shall be limited as required in the following:
  - (a) Fluoroscopic equipment shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of ten roentgens per minute at the point where the center of the useful beam enters the patient, except:
    - (i) during recording of fluoroscopic images; or
    - (ii) when provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the beam enters the patient unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
  - (b) In addition to the other requirements of this Rule equipment manufactured after August, 1974, which does not incorporate an automatic exposure control (e.g., automatic brightness control or ionization chamber control) shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the useful beam enters the patient except during the recording of fluoroscopic images or when provided with an optional high level control.
  - (c) Compliance with the provisions of ~~Subparagraph Item~~ (3) of this Rule shall be determined as follows:
    - (i) Movable grids and compression devices shall be removed from the useful beam during the measurement.
    - (ii) If the source is below the table, the exposure rate shall be measured one centimeter above the tabletop or cradle.
    - (iii) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
    - (iv) In a C-arm type fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.
  - (d) Periodic measurement of entrance exposure rate limits shall comply with the following:
    - (i) Such measurements shall be made every two years or after any maintenance of the system which might affect the exposure rate.
    - (ii) Results of these measurements shall be available or posted where any fluoroscopist may have ready access to them and shall be in the record required in Rule .0603(a)(2)(B) of this Section. Results of the measurements shall include the exposure rate, as well as the physical factors used to determine all data; the name of the person approved by the agency performing the measurements and the date the measurements were performed.
    - (iii) Entrance exposure rate shall be determined with the attenuation block in Rule .0602(a)(4) in the primary beam.
- (4) Radiation transmitted through the primary protective barrier of the fluoroscopic imaging assembly shall comply with the following requirements:
  - (a) The exposure rate resulting from transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two milliroentgens per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
  - (b) Measurements to determine compliance

with ~~Subparagraph~~ Sub-item (4)(a) of this Rule shall be in accordance with the following:

- (i) The exposure rate resulting from transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters;
  - (ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly, positioned 30 centimeters above the tabletop.
  - (iii) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters;
  - (iv) Movable grids and compression devices shall be removed from the useful beam during the measurement;
  - (v) The attenuation block shall be positioned in the useful beam ten centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.
- (5) During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated.
- (6) The source-skin distance shall not be less than:
- (a) 38 centimeters on stationary fluoroscopes,
  - (b) 30 centimeters on all mobile fluoroscopes, or
  - (c) 20 centimeters for image intensified fluoroscopes during surgical application.
- (7) Fluoroscopic timers shall meet the following requirements:
- (a) Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.
  - (b) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are

- (8) Mobile fluoroscopes, in addition to the other requirements of this Rule, shall provide image intensification.
- (9) Scattered radiation shall be controlled in accordance with the following requirements:
  - (a) A shielding device of at least 0.25 mm lead equivalent for covering the Bucky slot during fluoroscopy shall be provided.
  - (b) A shield of at least 0.25 mm lead equivalent, such as overlapping protective drapes or hinged or sliding panels, shall be provided to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine.
  - (c) Upon application to the agency with adequate justification, exceptions from ~~Subparagraphs~~ Sub-items (9)(a) or (9)(b) of this Rule may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers or where the protective barriers would interfere with the procedures.

*Statutory Authority G.S. 104E-7.*

#### **.0606 SYSTEMS OTHER THAN FLUOROSCOPIC AND DENTAL INTRAORAL**

(a) Unless specifically provided otherwise by the ~~Rules~~ rules in this Chapter, the requirements in this Rule shall apply to all x-ray systems, except for fluoroscopic and dental intraoral x-ray systems. The useful beam of x-ray systems subject to provisions of this Rule shall be limited to the area of clinical interest or the image receptor, whichever is smaller.

- (1) General purpose stationary and mobile x-ray systems shall meet the following special requirements:
  - (A) There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at a SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.
  - (B) Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray

field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

- (C) Notwithstanding ~~Subparagraphs~~ Parts (a)(1)(A) and (B) of this Rule, equipment manufactured before August 1, 1974 may employ fixed cones and diaphragms or variable collimators without beam defining lights.
- (2) In addition to the requirements of Subparagraph (a)(1) of this Rule, all stationary x-ray systems, except equipment originally manufactured before the effective date of this Rule, shall meet the following requirements:
  - (A) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;
  - (B) The beam limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;
  - (C) Indication of field size dimensions and SID's shall be specified in inches or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.
- (3) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.
- (4) Special purpose x-ray systems shall meet the following requirements:
  - (A) These systems shall be provided with means to limit the x-ray field in the plane of the image receptor so that

such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

- (B) Such systems shall also be provided with means to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.
- (C) The requirements in ~~Subparagraphs~~ Parts (a)(4)(A) and (B) of this Rule may be met with a system that meets the requirements for a general purpose x-ray system as specified in Subparagraph (a)(1) of this Rule or, when alignment means are also provided, as follows:
  - (i) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where each device has clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
  - (ii) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which each aperture is designated and indicating which aperture is in position for use.
- (b) Radiation exposure control devices shall meet the following requirements:
  - (1) Means shall be provided to terminate the exposure after a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition:
    - (A) Termination of exposure shall cause automatic resetting of the timer to its

- initial setting or to zero except during serial radiography, and
- (B) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided.
- (2) Control over x-ray exposures shall be in accordance with the following requirements:
- (A) A control shall be incorporated into each x-ray system such that the operator can terminate an exposure at any time except for serial radiography where means may be provided to permit completion of any single exposure of the series in process.
- (B) Each x-ray control shall be located in such a way as to meet the following criteria.
- (i) For stationary x-ray systems, the control shall be permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and
- (ii) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, except for equipment originally manufactured before the effective date of this Rule, a signal audible to the operator shall indicate that the exposure has terminated.
- (3) When an automatic exposure control (e.g., phototimer) is provided the following requirements shall be met, except equipment originally manufactured before the effective date of this Rule:
- (A) Indication shall be made on the control panel when this mode of operation is selected;
- (B) When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;
- (C) The minimum exposure time for all equipment other than that specified in ~~Subparagraph~~ Part (b)(3)(B) of this Rule shall be equal to or less than 1/60 second or a time interval re-

quired to deliver five mAs, whichever is greater;

- (D) Either the product of peak x-ray tube potential, current and exposure time shall be limited to not more than 60 kW per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
- (E) A visible signal shall indicate when an exposure has been terminated at the limits described in ~~Subparagraph~~ Part (b)(3)(D) of this Rule and manual resetting shall be required before further automatically timed exposures can be made.
- (4) When four timer tests are performed at identical timer setting equal to 5.0 seconds or less, the average time period (T) shall be greater than five times the difference between the maximum period ( $T_{max}$ ) and the minimum period ( $T_{min}$ ) in accordance with the formula:

$$T > 5(T_{max} - T_{min})$$

- (c) Source-skin or source-image receptor distance shall meet the following requirement:

All radiographic systems shall be provided with a durable, securely fastened means to limit the source-skin distance to at least 30 centimeters. This is considered to be met when the collimator or cone provides the required limits.

- (d) The exposure produced shall be reproducible to within the following criteria:

When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to be met if, when four exposures at identical technique factors are made, the value of the average exposure (E) is greater than five times the difference between the maximum exposure ( $E_{max}$ ) and the minimum exposure ( $E_{min}$ ) in accordance with the formula:

$$E > 5(E_{max} - E_{min})$$

- (e) Standby radiation from capacitor energy

storage equipment, when the exposure switch or timer is not activated, shall not exceed a rate of two milliroentgens per hour at five centimeters from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.

(f) Linearity

(1) When the equipment allows a choice of x-ray tube current settings, the average ratios of exposure to the indicated milliamperere-seconds product, i.e., mR/mAs, obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum, i.e.,  $|\text{mean of } x_1 - x_2| / \text{mean of } (x_1 + x_2) < \text{minus } 0.10$ , where the mean of  $x_1$  and  $x_2$  are the average mR/mAs values obtained at each of two consecutive tube current settings.

(2) Compliance shall be determined at the most commonly used mA stations by measuring mR/mAs at those stations and at one adjacent station to each.

(g) Timer accuracy

(1) For indicated values of 0.10 seconds and above, the measured value shall be within plus or minus 15 percent of the indicated values for equipment manufactured before August 1, 1974.

(2) For equipment manufactured after August 1, 1974, the deviation of measured values from indicated values shall not exceed the limits specified for that system by its manufacturer.

*Statutory Authority G.S. 104E-7.*

## SECTION .0700 - USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

### .0701 SCOPE

The provisions of this Section apply to all licensees who use sealed sources in the healing arts and are in addition to, and not in substitution for, other applicable provisions of the ~~Rules~~ rules of this Chapter.

*Statutory Authority G.S. 104E-7.*

### .0703 TELETHERAPY

(a) Any licensee authorized under Rule .0322 of this Chapter to use teletherapy units for treating humans shall cause full calibration measurements to be performed on each teletherapy unit.

(1) Such measurement shall be done at all of the following times:

(A) prior to the first use of the unit for treating humans;

(B) prior to treating humans whenever:

(i) spot-check measurements indicate that the output value differs by more than five percent from the value obtained at the last full calibration corrected mathematically for physical decay, or

(ii) following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location, or

(iii) following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(C) at intervals not exceeding one year.

(2) Full calibration measurements required by Subparagraph (a)(1) of this Rule shall include determination of:

(A) the exposure rate or dose rate to an accuracy within plus or minus three percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;

(B) the congruence between the radiation field and the field indicated by the light beam localizing device;

(C) the uniformity of the radiation field and its dependence upon the orientation of the useful beam;

(D) timer accuracy; and

(E) the accuracy of all distance-measuring devices used for treating humans.

(3) Full calibration measurements shall be made in accordance with the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine (Physics in Medicine and Biology, Vol. 16, No. 3, 1971, pp. 379-396).

(4) The exposure rate or dose rate values determined in ~~Subparagraph~~ Part (a)(2)(A) of this Rule shall be corrected mathematically for physical decay for intervals not exceeding one month.

(5) Full calibration measurements required by Subparagraph (a)(1) of this Rule and physical decay corrections required by

Subparagraph (a)(4) of this Rule shall be performed by an expert qualified by training and experience in accordance with Subparagraph (d)(1) of this Rule.

(b) Any licensee authorized under Rule .0322 of this Chapter to use teletherapy units for treating humans shall cause spot-check measurements to be performed on each teletherapy unit at intervals not exceeding one month.

(1) Required spot-check measurements shall include determination of:

- (A) timer accuracy;
- (B) the congruence between the radiation field and the field indicated by the light beam localizing device;
- (C) the accuracy of all distance-measuring devices used for treating humans;
- (D) the exposure rate, dose rate, or a quantity related in a known manner to these rates for one typical set of operating conditions; and
- (E) the difference between the measurement made in ~~Subparagraph~~ Part (b)(1)(D) of this Rule and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(2) Required spot-check measurements shall be performed in accordance ~~with~~ with procedures established by an expert qualified by training and experience in accordance with Paragraph (d) of this Rule.

(c) Any licensee responsible for the performance of full calibration ~~and~~ or spot-check measurements shall be required to calibrate the instruments used in making such determinations.

(1) Full calibration measurements required by Paragraph (a) of this Rule shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.

(2) Spot-check measurements required by Paragraph (b) of this Rule shall be performed using a dosimetry system that has been calibrated in accordance

with Subparagraph (c)(1) of this Rule. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with Subparagraph (c)(1) of this Rule. This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

(d) The licensee shall determine if a person is an expert qualified by training and experience to calibrate a teletherapy unit and establish procedures for and review the results of spot-check measurements.

(1) The licensee shall determine that the expert is qualified by his:

- (A) being certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma-ray physics, or x-ray and radium physics; or
- (B) having the following minimum training and experience:
  - (i) a master's or doctor's degree in physics, biophysics, radiological physics or health physics;
  - (ii) one year of full-time training in therapeutic radiological physics; and
  - (iii) one year of full-time experience in a radiotherapy facility including personal calibration and spot check of at least one teletherapy unit.

(2) The licensee who has his teletherapy units calibrated by persons who do not meet the criteria for minimum training and experience stated in ~~Subparagraph~~ Part (d)(1)(B) of this Rule may request a license amendment excepting them from these requirements.

- (A) Such request shall include:
  - (i) the name of the proposed qualified expert;
  - (ii) a description of his training and experience including information similar to that specified in ~~Subparagraph~~ Part (d)(1)(B) of

this Rule:

- (iii) reports of at least one calibration and spot-check program based on measurements personally made by the proposed expert within the last ten years; and
- (iv) written endorsement of the technical qualifications of the proposed expert from personal knowledge by a physicist certified by the American Board of Radiology in one of the specialties listed in Subparagraph Part (d)(1)(A) of this Rule.

(B) The individual's qualifications will be evaluated by the Division of Radiation Protection, North Carolina Department of Environment, Health, and Natural Resources.

(C) The amendment request must be addressed to the agency at the address found in Rule .0111 of this Chapter.

(e) The licensee shall maintain, for inspection by the agency, records of the measurements, tests, corrective actions, and instrument calibrations made under Paragraphs (a), (b), and (c) of this Rule, and records of the licensee's evaluation of the qualified expert's training and experience made under Paragraph (d) of this Rule for the following periods of time:

- (1) Records of the full calibration measurements under Paragraph (a) of this Rule and the calibration of the instruments used to make these measurements under Paragraph (c) of this Rule shall be preserved for five years after completion of the calibration.
- (2) Records of the spot-check measurements and corrective actions under Paragraph (b) of this Rule and the calibration of instruments used to make spot-check measurements under Paragraph (c) of this Rule shall be preserved for two years after completion of the spot-check measurements and corrective actions.
- (3) Records of the licensee's evaluation of the qualified expert's training and experience under Paragraph (d) of this Rule shall be preserved for five years after the qualified expert's last performance of a full calibration on the licensee's teletherapy unit.

(f) Each teletherapy room shall be equipped with

a radiation monitoring device which continuously monitors the teletherapy beam condition and is equipped with a back-up battery power supply for emergency operation.

- (1) This device shall energize a visible signal to make the operator continuously aware of teletherapy beam conditions in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure.
- (2) Operating procedures shall be modified to require daily operational testing of the installed radiation monitor.
- (3) If a radiation monitor is inoperable for any reason, any person entering the teletherapy room shall use a properly operating portable radiation survey instrument or a personal dosimeter with an audible alarm to monitor for any malfunction of the source exposure mechanism which may have resulted in an exposed or partially exposed source.
- (4) Survey instruments or dosimeters shall be tested daily before use.

(g) The licensee shall cause each teletherapy unit used to treat humans to be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(h) Inspection and servicing of the teletherapy unit shall be performed by persons specifically authorized to perform such services by a specific license issued by the agency, the U.S. Nuclear Regulatory Commission or an agreement state.

*Statutory Authority G.S. 104E-7(a)(2).*

## SECTION .0900 - REQUIREMENTS FOR PARTICLE ACCELERATORS

### .0902 LICENSING REQUIREMENTS

No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a license issued pursuant to these Regulations Rules or as otherwise provided for in these Regulations Rules. The general procedures for licensing of particle accelerator facilities are included in Section .0903 of this Chapter.

*Statutory Authority G.S. 104E-7.*

## SECTION .1000 - NOTICES: INSTRUCTIONS: REPORTS AND



## **INSPECTIONS**

### **.1001 SCOPE**

This Section establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in work under a license or registration and options available to such individuals in connection with agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and rules, orders and licenses issued thereunder regarding radiological working conditions. The ~~regulations~~ rules in this Section apply to all persons who receive, possess, use, own or transfer sources of radiation licensed by or registered with the agency pursuant to the ~~Regulations~~ rules in Sections .0200, .0300, .0900 and .1200 of this Chapter.

*Statutory Authority G.S. 104E-7; 104E-12.*

### **.1006 CONSULTATION WITH WORKERS**

(a) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of this Chapter and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the Act, provisions of this Chapter, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of Rule .1007 of this Section.

(c) The provisions of Paragraph (b) of this Rule shall not be interpreted as authorization to disregard instructions pursuant to Rule .1003 of this Section.

*Statutory Authority G.S. 104E-7; 104E-10.*

## **SECTION .1100 - FEES**

### **.1102 PAYMENT DUE**

(a) All fees established in this Section shall be due on the effective date of this Rule and on the first day of July of each subsequent year.

(b) Notwithstanding Paragraph (a) of this Rule, when a new license or registration is issued by the agency after the first day of July of any year, the

initial fee shall be due on the date of issuance of the license or registration.

(c) The initial fee in Paragraph (b) of this Rule shall be computed as follows:

- (1) When any new license or registration is issued before the first day of January of any year, the initial fee shall be the full amount specified in Rule .1105 of this Section; and
- (2) When any new license or registration is issued on or after the first day of January of any year, the initial fee shall be one-half of the amount specified in Rule .1105 of this Section.

(d) All fees received by the agency pursuant to provisions of this Section shall be nonrefundable.

(e) Each licensee or registrant shall pay all fees by check or money order made payable to "Division of Radiation Protection" and mail such payment to: Division of Radiation Protection, North Carolina Department of Environment, Health, and Natural Resources, P. O. Box 27687, Raleigh, North Carolina 27611-7687. Such payment may be delivered to the agency at its office located at 3825 Barrett Drive, Raleigh, North Carolina 27609-7221.

*Statutory Authority G.S. 104E-9(8); 104E-19(a).*

### **.1103 NOTICES OF PAYMENT DUE**

Within five days after the due dates established in Paragraphs (a) and (b) of Rule .1102 of this Section, the agency shall mail to each licensee and registrant, who has not already submitted payment, a notice which indicates the due date, delinquent date and the amount of fees due.

*Statutory Authority G.S. 104E-9(8); 104E-19(a).*

### **.1104 DELINQUENT AND UNCOLLECTIBLE FEES**

(a) Payment of fees established in this Section shall be delinquent, if not received by the agency within 60 days after the due date specified in Paragraphs (a) and (b) of Rule .1102 of this Section.

(b) If a licensee or registrant remits a fee in the form of a check or other instrument which is uncollectible from the paying institution, the agency shall notify the licensee or registrant by certified mail and allow the licensee or registrant 15 days to correct the matter.

(c) If payment of fees is uncollectible from the paying institution or not submitted to the agency by the delinquent date, the agency may institute

appropriate legal action to collect.

*Statutory Authority G.S. 104E-9(8); 104E-19(a).*

## SECTION .1200 - LAND DISPOSAL OF RADIOACTIVE WASTE

### .1202 DEFINITIONS

As used in this Section, the following definitions shall apply.

- (1) "Active maintenance" means any significant remedial activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in Rules .1223 and .1224 of this Section are met. Such active maintenance includes ongoing activities such as the pumping and treatment of water from a disposal unit or one-time measures such as replacement of disposal unit cover. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep such as mowing grass.
- (2) "Buffer zone" is a portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.
- (3) "Chelating agent" means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g., citric acid, carboic acid, and gluconic acid).
- (4) "Commencement of construction" means clearing of land, excavation, or other substantial action that would adversely affect the environment of a land disposal facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values.
- (5) "Custodial agency" means the North Carolina Low-Level Radioactive Waste Management Authority.
- (6) "Disposal" means the isolation of waste from the biosphere inhabited by man and his food chains by emplacement in a land disposal facility.
- (7) "Disposal site" means that portion of a land disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone.
- (8) "Disposal system" means the components relied on to ensure that the land disposal facility meets the performance objectives and other requirements of this Section. These components include the site and its characteristics, the facility and disposal unit design, and engineered barriers therein, the waste, facility operations and closure, intruder barriers and institutional control.
- (9) "Disposal unit" means a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal, the disposal unit is usually a trench.
- (10) "Engineered barrier" means engineered barrier as defined in G.S. 104E-5(7a).
- (11) "Explosive material" means any chemical compound, mixture, or device, which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.
- (12) "Government agency" means any executive department, commission, independent establishment, or corporation, wholly or partly owned by the United States of America or the State of North Carolina and which is an instrumentality of the United States or the State of North Carolina; or any board, bureau, department, division, service, office, officer, authority, administration, or other establishment in the executive branch of the government.
- (13) "Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.
- (14) "Hydrogeologic unit" means any soil or rock unit or zone which by virtue of its porosity or permeability, or lack thereof, has a distinct influence on the storage or movement of groundwater.
- (15) "Inadvertent intruder" means a person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, or other pursuits in which the person might be unknowingly

- exposed to radiation from the waste.
- (16) "Intruder barrier" means a sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in this Section, or engineered structures that provide equivalent protection to the inadvertent intruder.
- (17) "Institutional control" means control of the site after the site is closed and stabilized and responsibility for all disposed waste and site maintenance is assumed by the custodial agency.
- (18) "Land disposal facility" means low-level radioactive waste disposal facility as defined in G.S. 104E-5(9c).
- (19) "Low-level radioactive waste" means low-level radioactive waste as defined in G.S. 104E-5(9a) and includes naturally occurring and accelerator produced radioactive material which is not subject to regulation by the U.S. Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended, and is suitable for land disposal under the provisions in this Section.
- (20) "Mixed waste" means waste that satisfies the definition of low-level radioactive waste in ~~Subparagraph~~ Item (19) of this Rule and contains hazardous waste that either:
- (a) is listed as a hazardous waste in Subpart D of 40 CFR Part 261 or
  - (b) causes the low-level radioactive waste to exhibit any of the hazardous waste characteristics identified in Subpart C of 40 CFR Part 261.
- (21) "Monitoring" means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.
- (22) "Near-surface disposal facility" means a land disposal facility in which waste is disposed of within approximately the upper 30 meters of the earth's surface.
- (23) "Reconnaissance level information" is any information or analysis that can be retrieved or generated without the performance of new comprehensive site-specific investigations. Reconnaissance level information includes but is not limited to drilling records required by state agencies, other

- Divisions of this Department, and other relevant published scientific literature.
- (24) "Retrieval" means a remedial action for removal of Class B and C waste from a disposal unit.
- (25) "Shallow land burial" means shallow land burial as defined in G.S. 104E-5(14a).
- (26) "Site closure and stabilization" means those actions that are taken upon completion of operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.
- (27) "State" means the State of North Carolina.
- (28) "Surveillance" means monitoring and observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion, and compliance with other license and regulatory requirements.
- (29) "Waste" means low-level radioactive waste that is acceptable for disposal in a land disposal facility. For the purpose of this Section, the words "waste" and "low-level radioactive waste" have the same meaning.

*Statutory Authority G.S. 104E-5; 104E-7; 104E-10; 104E-25.*

### **.1203 LICENSE REQUIRED**

(a) No person may receive, possess, and dispose of waste from other persons at a land disposal facility unless authorized by a license issued by the agency pursuant to the ~~Rules~~ rules in this Section and the ~~Rules~~ rules in Section .0300 of this Chapter.

(b) Each person shall file an application with the agency pursuant to Rule .0317 of this Chapter and obtain a license as provided in this Section before commencement of construction of a land disposal facility. Failure to comply with this requirement may be grounds for denial of a license.

*Statutory Authority G.S. 104E-7; 104E-10(b); 104E-25; 104E-26.*

### **.1205 GENERAL INFORMATION**

(a) The general information shall include each of the following:

- (1) identity of the applicant including:
  - (A) the full name, address, telephone number, and description of the

- business or occupation of the applicant;
  - (B) if the applicant is a partnership, the name and address of each partner and the principal location where the partnership does business;
  - (C) if the applicant is a corporation or an unincorporated association.
    - (i) the state where it is incorporated or organized and the principal location where it does business, and
    - (ii) the names and addresses of its directors and principal officers;
  - (D) if the applicant is acting as an agent or representative of another person in filing the application, all information required under this Paragraph shall be supplied with respect to the other person; and
  - (E) if the applicant proposes to contract the operation of the disposal facility to another person, the full name, address, and telephone number of the management contractor, the full name and address of each applicable principal, partner, or director of the contractor, the state where it is organized, and the principal location where it does business;
- (2) qualifications of the applicant:
- (A) the applicable organizational structure of the applicant, both off site and on site, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;
  - (B) the technical qualifications, including training, experience, and professional licensure, registration or certification of the applicant and members of the applicant's staff to engage in the proposed activities, to include the minimum training, experience, and professional licensure, registration or certification requirements for personnel filling key positions described in Subparagraph Part (a)(2)(A) of this Rule;
  - (C) a description of the applicant's personnel training program;
  - (D) the plan to maintain an adequate complement of trained personnel on site to carry out waste receipt, handling, and disposal operations in a safe manner;
  - (E) prior experience in the generation, processing, use, transportation or disposal of radioactive material or in the treatment, storage, transportation or disposal of hazardous waste including copies of all notices of violations; assessments of any administrative, civil, criminal or other penalties in connection therewith; and all information as to any finding or determination that the applicant engaged in any of the above mentioned activities without having in effect any license or permit required for such activity;
  - (F) disclosure of any prior determination of civil or criminal liability with respect to any other federal or state law or regulation, including but not limited to any law or regulation governing the transfer of securities, which may reflect on the applicant's character, reputation or ability to comply with all requirements imposed on a licensee; and
  - (G) upon request by the agency, a copy of any application which the applicant may previously have submitted for any license or permit required for any activity listed in Subparagraph Part (a)(2)(E) of this Rule; information as to the disposition of such application including a copy of the license or permit, information as to any restriction, suspension, revocation or cancellation of any such license or permit; and any other information which may be requested by the agency as to the applicant's experience and operating practices with respect to the activities listed in Subparagraph Part (a)(2)(E) of this Rule;
- (3) a description of:
- (A) the location of the proposed disposal site;
  - (B) the general character of the proposed activities;
  - (C) the types and quantities of waste to be received, possessed, and disposed of;
  - (D) plans for use of land disposal facility for purposes other than disposal of wastes during operation, after closure

- or both;
  - (E) the proposed facilities and equipment;
  - (F) the proposed manifest and recording system;
  - (G) the treatment of any waste to be shipped off site;
  - (H) anticipated operating life of the facility; and
  - (I) the preclicensing and operational public information program which addresses
    - (i) state and local government;
    - (ii) media and public;
    - (iii) acceptability within the community where the facility is to be located; and
    - (iv) the program being implemented to ensure concerns of the public are being met; and
  - (4) proposed time schedules for construction, receipt of waste, and first emplacement of waste at the proposed land disposal facility.
- (b) The following are additional requirements applicable to the information required in ~~Subparagraphs~~ Parts (a)(2)(E) through (G) of this Rule:
- (1) All information will be provided by the applicant with respect to the applicant itself, any predecessor or parent entity, any officer, director, partner or other principal of the applicant; any stockholder or other entity holding five percent or more of the stock of, or other interest in, the applicant; and any subsidiary or other entity in which the applicant has an interest.
  - (2) All information will be provided for a period of not less than 20 years or as may be determined by the agency with respect to a particular applicant or class of information.
  - (3) With the approval of the agency, the applicant may submit any of the information, except as to the disposal of low-level radioactive waste, in summary form; provided that any summary must fairly and accurately reflect the applicant's experience and operating practices and must indicate the nature and extent of all violations of law and applicable regulations.
  - (4) The agency may request that the applicant provide any supplemental information needed to effect the purpose of ~~Subparagraphs~~ Parts

(a)(2)(E) through (G) of this Rule. All such supplementary information provided by or on behalf of the applicant will become a part of the application.

*Statutory Authority G.S. 104E-7; 104E-10(b); 104E-10.1; 104E-25; 104E-26.*

## .1210 FINANCIAL INFORMATION

(a) The financial information shall be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and meet other financial assurance requirements of this Section. In addition to information required in Rule .1205 of this ~~Chapter~~ Section, the applicant shall provide the following financial information:

- (1) financial organization of the company;
- (2) a list of all subsidiary companies and their locations;
- (3) audited financial statements for the most recent calendar or fiscal year;
- (4) interim statements, if it has been six months or more since the end of the reporting year;
- (5) a detailed schedule of liability insurance coverage applicable to low-level radioactive waste, listing:
  - (A) each insurance company's name,
  - (B) amount of coverage,
  - (C) any limitations on coverage,
  - (D) duration of insurance policies, and
  - (E) whether the company is licensed by the North Carolina Insurance Commissioner;
- (6) status and nature of any outstanding civil action to which the applicant is a party, and of any administrative or criminal proceeding against the applicant; and the same information with respect to any business entity which holds an interest of five percent or more in the applicant, or in which the applicant holds any interest; subject to the following provisions:
  - (A) upon request by the agency, the information required by this Subparagraph shall include a copy of any document which is a part of public record in any such action or proceeding;
  - (B) with the approval of the agency, the applicant may submit any of the information required by this

Subparagraph in summary form, provided that any summary must fairly and accurately reflect the scope and content of such information:

- (C) with the approval of the agency, the applicant may exclude information which would otherwise be required by this Subparagraph provided that the applicant identifies the types of information to be omitted and satisfies the agency that such types of information are not material to the applicant's ability to operate a facility under this Section; and

- (D) unless specifically requested by the agency, the following types of actions if brought in North Carolina, or equivalent types of actions if brought in any other jurisdiction, are excluded from the reporting requirements of this Subparagraph:

- (i) small claims actions as defined in G.S. 7A-210,
- (ii) infractions as defined in G.S. 14-3.1, and
- (iii) misdemeanors under Chapter 20 (Motor Vehicles) of the General Statutes; and

- (7) details of any other resources such as reserves or bonds to cover potential damages.

(b) The applicant shall describe the financial responsibility and liability coverage for:

- (1) all injuries to public, property, workers and environment;
- (2) failure to operate as designed; and
- (3) post-closure monitoring and surveillance.

(c) The information required in Paragraphs (a) and (b) of this Rule shall be updated annually to the extent that such information is not provided in the annual certified financial statement required in Rule .1238 of this Section.

*Statutory Authority: G.S. 104E-7; 104E-10(b); 104E-10.1; 104E-25; 104E-26.*

## .1215 CONDITIONS OF LICENSE

(a) A license issued under this Section, or any right thereunder, may not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the agency finds, after securing full information, that the transfer is in accordance with

the provisions of the North Carolina Radiation Protection Act (Act) and gives its consent in writing in the form of a license amendment.

(b) At any time before termination of the license, the licensee shall submit written statements under oath upon request of the agency to enable the agency to determine whether or not the license should be modified, suspended, or revoked.

(c) The license will be transferred to the custodial agency only on the full implementation of the final closure plan as approved by the agency, including postclosure observation and maintenance.

(d) The licensee shall be subject to the provisions of the Act now or hereafter in effect, and to all rules and orders of the agency. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to, or by reason of rules and orders issued in accordance with terms of the Act.

(e) Any license may be revoked, suspended or modified in whole or in part for any material false statement in the application or any misstatement of fact required under the Act, or because of conditions revealed by any application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a license on the original application, or for failure to operate the facility in accordance with the terms of the license, or for any violation of, or failure to observe any of the terms and conditions of the Act, or any rule, license or order of the agency.

(f) Each person licensed by the agency pursuant to the ~~Rules~~ rules in this Section shall confine possession and use of radioactive materials to the locations and purposes authorized in the license.

(g) No waste may be disposed of until the agency has inspected the land disposal facility and has found it to be in conformance with the description, design, and construction described in the application for a license.

(h) The agency may incorporate in any license at the time of issuance, or thereafter, by appropriate rule or order, additional requirements and conditions with respect to the licensee's receipt, possession, and disposal of waste as it deems appropriate or necessary in order to:

- (1) protect the health and safety of the public and the environment, or minimize danger to life or property; and
- (2) require reports and the keeping of records, and to provide for inspections of activities under the license that may be necessary or appropriate to

effectuate the purposes of the Act and rules thereunder.

(i) The agency may incorporate in any license at the time of issuance, or thereafter, by appropriate rule or order, a requirement that the licensee provide the agency with continuing information with respect to any information required as a part of the license application.

(j) Except as provided otherwise by the agency pursuant to Paragraph (h) of this Rule and consistent with G.S. 104E-25(h), the licensee shall not accept or dispose of:

- (1) liquid waste which has not been solidified in a manner deemed acceptable by the agency;
- (2) any waste containing chelating agents in concentrations greater than one-tenth of one percent by weight unless:
  - (A) the chelating agent content does not exceed eight percent by weight, and
  - (B) the waste has been solidified and meets the stability requirements for class B and C waste as may be specified by the agency after consideration of current regulatory guides on waste form of the U.S. Nuclear Regulatory Commission, provided however that high integrity containers alone are not acceptable to achieve this stability requirement; and
- (3) such other waste as the agency may prohibit as necessary to ensure that the performance objectives of this Section will be met.

(k) Each license will be issued for a period of five years from the date of issuance. The authority to dispose of wastes expires on the date stated in the license except as provided in Rule .1217 of this Section.

*Statutory Authority G.S. 104E-7; 104E-10(b); 104E-12; 104E-13(a); 104E-25; 104E-26.*

## **.1218 CONTENTS OF APPLICATION FOR CLOSURE**

(a) Prior to final closure of the disposal site, or as otherwise directed by the agency, the applicant shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the disposal site closure plan included as part of the license application submitted under Rule .1206(16) of this Section that includes each of the following:

- (1) any additional geologic, geochemical, hydrologic, or other data obtained

during the operational period pertinent to the long-term containment of emplaced wastes;

- (2) the results of tests, experiments, or any other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or any other tests, experiments, or analyses pertinent to the long-term containment of emplaced waste within the disposal site;
- (3) any proposed revision of plans for:
  - (A) decontamination and dismantlement of surface facilities;
  - (B) backfilling of excavated areas; or
  - (C) stabilization of the disposal site for postclosure care; and
- (4) any significant new information regarding the environmental impact of closure activities and long-term performance of the disposal site.

(b) Upon review and consideration of an application to amend the license for closure submitted in accordance with Paragraph (a) of this Rule, the agency may issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of this Section will be met.

*Statutory Authority G.S. 104E-7; 104E-9(3); 104E-10; 104E-10.1; 104E-18; 104E-25; 104E-26; 104G-13; 104G-14.*

## **.1220 TRANSFER OF LICENSE**

Following closure and the period of postclosure observation and maintenance, the licensee may apply for an amendment to transfer the license to the custodial agency. The license shall be transferred when the agency finds:

- (1) that the closure of the disposal site has been made in conformance with the licensee's disposal site closure plan, as amended and approved as part of the license;
- (2) that reasonable assurance has been provided by the licensee that the performance objectives of this Section are met;
- (3) that any funds and necessary records for care will be transferred to the Long-Term Care Fund and the custodial agency, respectively;
- (4) that sufficient funds have accumulated in the Long-Term Care Fund to support

anticipated agency and custodial agency costs for all future observation, monitoring, maintenance and remedial actions;

- (5) that the postclosure monitoring program is operational for implementation by the custodial agency; and
- (6) that the custodial agency or the federal agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under ~~Subparagraph Item~~ (7) of Rule .1214 of this Section will be met.

*Statutory Authority G.S. 104E-7; 104E-10; 104E-10.1; 104E-12; 104E-16; 104E-18; 104E-25; 104E-26; 104G-13; 104G-14.*

### **.1221 TERMINATION OF LICENSE**

(a) Following any period of institutional control needed to meet the requirements found necessary under Rule .1214 of this Section, the custodial agency may apply for an amendment to terminate the license.

(b) This application shall be filed, and will be reviewed, in accordance with the provisions of ~~Rules~~ Rule .1211 of this Section and Paragraph (a) of this Rule.

(c) A license will be terminated only when the agency finds:

- (1) that the institutional control requirements found necessary under ~~Subparagraph Item~~ (7) of Rule .1214 of this Section have been met; and
- (2) that any additional requirements resulting from new information developed during the institutional control period have been met, and that permanent monuments or markers warning against intrusion have been installed.

*Statutory Authority G.S. 104E-7; 104E-10; 104E-25; 104G-13; 104G-14.*

### **.1223 PROTECTION OF POPULATION FROM RELEASES OF RADIOACTIVITY**

(a) The design goal of the engineered barrier and other requirements in this Section is confinement of the disposed waste and contained radioactivity for at least the designed life of the required engineered barriers, with reasonable

assurance that any release of radioactivity or radiation will not exceed the limits stated in Paragraph (b) of this Rule and will be as low as reasonably achievable as provided in Paragraph (c) of this Rule.

(b) Land disposal facilities shall not cause external radiation levels or release concentrations of radioactive material to the general environment in groundwater, surface water, air, soil, plants, or animals that result in an annual equivalent dose to any member of the public, above background as determined in accordance with Rule .1231 of this Section, exceeding:

- (1) 25 millirems to the whole body,
- (2) 75 millirems to the thyroid, or
- (3) 25 millirems to any other organ.

(c) In accordance with the ALARA plan required by Rule .1206~~(12)~~ of this Section, the licensee shall maintain releases of radioactivity in effluents to the general environment and resultant radiation dose to the public as low as reasonably achievable below the limits imposed in Paragraph (b) of this Rule.

*Statutory Authority G.S. 104E-7; 104E-10; 104E-25; 104E-26.*

### **.1227 TECHNICAL REQUIREMENTS FOR LAND DISPOSAL FACILITIES**

The technical requirements for land disposal facilities are set forth in Rules .1228 through .1234 of this Section. ~~Section.~~

*Statutory Authority G.S. 104E-7; 104E-10; 104E-25; 104E-26.*

### **.1229 SITE DESIGN FOR LAND DISPOSAL**

(a) Shallow land burial is prohibited as provided in G.S. 104E-20(b).

(b) Site design features shall be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.

(c) The disposal site design and operation shall be compatible with the disposal site closure and stabilization plan and lead to disposal site closure that provides reasonable assurance that the performance objectives of this Section will be met.

(d) The disposal site shall be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives of this Section will be met.

(e) Covers shall be designed to minimize water infiltration, to direct percolating or surface water away from the disposed waste, and to resist



degradation by surface geologic processes and biotic activity.

(f) Surface features shall direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance.

(g) The disposal site shall be designed to minimize the contact of water with waste during storage, the contact of standing water with waste during disposal, and the contact of percolating or standing water with wastes after disposal.

(h) The disposal units shall incorporate engineered barriers. The disposal units and incorporated engineered barriers shall be designed and constructed to meet the performance objectives, technical requirements and design criteria in G.S. 104E-25 and the following additional requirements:

- (1) The engineered barriers shall provide reasonable assurance that they will complement, and where appropriate improve, the land disposal facility's ability to isolate the radioactive waste through the institutional control period;
- (2) Engineered barrier structural integrity shall be maintained under normal and abnormal conditions of operation;
- (3) Engineered barriers shall prevent contact between the surrounding earth and the waste, except for earth that may be used as fill material within the disposal unit; and
- (4) The disposal units shall be constructed or emplaced in a manner which will ensure that the bottom of the disposal facility is at least seven feet above the seasonal high water table or more if necessary to meet the performance objectives of this Section.

(i) The licensee shall develop, operate and maintain the site in a manner that will not diminish the hydrogeological performance of the site below the requirements contained in the Rules rules of this Section.

*Statutory Authority G.S. 104E-7; 104E-10; 104E-25; 104E-2.*

#### **.1239 TESTS AT LAND DISPOSAL FACILITIES**

Each licensee shall perform, or permit the agency to perform, any tests the agency deems appropriate or necessary for the administration of the Rules rules of this Section, including tests of:

- (1) wastes and facilities used for the receipt, storage, handling, and disposal of wastes;
- (2) radiation detection and monitoring instruments; and
- (3) other equipment and devices used in connection with the receipt, possession, handling, storage, or disposal of waste.

*Statutory Authority G.S. 104E-7; 104E-10(b); 104E-25; 104E-26.*

#### **.1240 AGENCY INSPECTIONS OF LAND DISPOSAL FACILITIES**

(a) Each licensee shall afford to the agency at all reasonable times opportunity to inspect:

- (1) waste not yet disposed of;
- (2) the premises, equipment, operations, and facilities in which wastes are received, possessed, handled, treated, stored or disposed of; and
- (3) records kept by the licensee pursuant to the applicable Rules rules of this Chapter.

(b) Authorized representatives of the agency may copy and take away copies of, for the agency's use, any record required to be kept pursuant to provisions of this Section.

*Statutory Authority G.S. 104E-7; 104E-10(b); 104E-11; 104E-12; 104E-25; 104E-26.*

#### **SECTION .1300 - REQUIREMENTS FOR WIRELINE-SERVICE OPERATORS AND SUBSURFACE-TRACER STUDIES**

##### **.1306 TRANSPORT PRECAUTIONS**

Transport containers shall be ~~physically~~ physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

*Statutory Authority G.S. 20-167.1; 104E-7; 104E-10(b); 104E-15(a).*

##### **.1308 LEAK TESTING OF SEALED SOURCES**

(a) Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the agency for six months after the next required leak test is performed or until transfer or disposal of the sealed source.

(b) Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the agency, the U.S. Nuclear Regulatory

Commission, an agreement state, or a licensing state. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample.

(c) Each sealed source of radioactive material shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

(d) If the test reveals the presence of 0.005 microcurie or more of ~~leakage~~ leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these Rules. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the agency.

(e) The following sources are exempt from the periodic leak test and notification requirements of this Rule:

- (1) hydrogen-3 sources;
- (2) sources of radioactive material with a half-life of 30 days or less;
- (3) sealed sources of radioactive material in gaseous form;
- (4) sources of beta- and/or gamma-~~emitting~~ emitting radioactive material with an activity of 100 microcuries or less; and
- (5) sources of alpha-emitting radioactive material with an activity of ten microcuries or less.

*Statutory Authority G.S. 104E-7; 104E-12(a).*

### .1309 QUARTERLY INVENTORY

Each licensee shall conduct a quarterly physical inventory to account for all ~~source~~ sources of radiation. Records of inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the

name of the individual conducting the inventory.

*Statutory Authority G.S. 104E-7; 104E-12(a)(1).*

### .1310 UTILIZATION RECORDS

(a) Each licensee shall maintain current utilization records showing the following information for each source of radiation:

- (1) make, model number, and a serial number or a description of each source of radiation used;
- (2) the identity of the well-logging supervisor or field unit to whom assigned;
- (3) locations where used and dates of use; and
- (4) in the case of tracer materials and radioactive markers, the radionuclide and activity used in a particular well.

(b) The licensee shall maintain the utilization records, required in Paragraph (a) of this Rule, for inspection by the agency for a period of two years from the date of the recorded event(s).

*Statutory Authority G.S. 104E-7; 104E-12(a)(1).*

### .1313 INSPECTION AND MAINTENANCE

(a) Each licensee shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and proper physical condition. The licensee shall maintain records of inspection and maintenance for a period of two years for inspection by the agency.

(b) If any inspection conducted pursuant to Paragraph (a) of this Rule reveals damage to labeling or components critical to radiation safety, the licensee shall remove the device from service until repairs have been made.

(c) The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

*Statutory Authority G.S. 104E-7.*

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*Notice is hereby given in accordance with G.S. 150B-21.2 that the EHNR-Commission for Health Services intends to amend rules cited as 15A*

NCAC 13A .0001 - .0014 and adopt rule cited as 15A NCAC 13A .0018.

*The proposed effective date of this action is April 1, 1993.*

*The public hearing will be conducted at 1:30 p.m. on January 20, 1993 at the Highway Building, First Floor Auditorium, 1 South Wilmington Street, Raleigh, North Carolina.*

*Reason for Proposed Action: To clarify and establish a uniform and consistent approach to the regulation of off-site recycling facilities; to set fees for permit modifications; and to comply with federal rules promulgated between July 10, 1992 and September 10, 1992, which are required to remain in compliance with EPA authorization requirements.*

*Comment Procedures: All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629, (919)733-4618. If you desire to speak at the public hearing, notify John P. Barkley at least 3 days prior to the public hearing. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or address proposed changes from staff pursuant to comments made during the public hearing process.*

*IT IS VERY IMPORTANT THAT ALL INTERESTED AND POTENTIALLY AFFECTED PERSONS, GROUPS, BUSINESSES, ASSOCIATIONS, INSTITUTIONS, OR AGENCIES MAKE THEIR VIEWS AND OPINIONS KNOWN TO THE COMMISSION FOR HEALTH SERVICES THROUGH THE PUBLIC HEARING AND COMMENT PROCESS, WHETHER THEY SUPPORT OR OPPOSE ANY OR ALL PROVISIONS OF THE PROPOSED RULES. THE COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).*

## CHAPTER 13 - SOLID WASTE MANAGEMENT

### SUBCHAPTER 13A - HAZARDOUS WASTE MANAGEMENT

#### .0001 GENERAL

(a) The Hazardous Waste Section of the Solid Waste Management Division shall administer the hazardous waste management program for the State of North Carolina.

(b) In applying the federal requirements incorporated by reference throughout this Subchapter, the following substitutions or exceptions shall apply:

- (1) "Department of Environment, Health, and Natural Resources" shall be substituted for "Environmental Protection Agency" except in 40 CFR 262.51 through 262.54, 262.56, 262.57 where references to the Environmental Protection Agency shall remain without substitution;
- (2) "Secretary of the Department of Environment, Health, and Natural Resources" shall be substituted for "Administrator," "Regional Administrator" and "Director" except for 40 CFR 262.55 through 262.57, 264.12(a), 268.5, 268.6, 268.42(b) and 268.44 where the references to the Administrator, Regional Administrator, and Director shall remain without substitution; and
- (3) An "annual report" shall be required for all hazardous waste generators, treaters, storers, and disposers rather than a "biennial report".

(c) In the event that there are inconsistencies or duplications in the requirements of those Federal rules incorporated by reference throughout this Subchapter and the State rules set out in this Subchapter, the provisions incorporated by reference shall prevail except where the State rules are more stringent.

(~~e~~) (~~d~~) 40 CFR 260.1 through 260.3 (Subpart A), "General," have been incorporated by reference including subsequent amendments and editions.

(~~d~~) (~~e~~) 40 CFR 260.11, "References", has been incorporated by reference including subsequent amendments and editions.

(~~e~~) (~~f~~) Copies of all materials in this Subchapter may be inspected or obtained as follows:

- (1) Persons interested in receiving rule-making notices concerning the North Carolina Hazardous Waste

Management Rules must submit a written request to the Hazardous Waste Section, P.O. Box 27687, Raleigh, N.C. 27611-7687. A check in the amount of fifteen dollars (\$15.00) made payable to The Hazardous Waste Section must be enclosed with each request. Upon receipt of each request, individuals will be placed on a mailing list to receive notices for one year.

- (2) Material incorporated by reference in the Federal Register may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 at a cost of three hundred and forty dollars (\$340.00) per year. Federal Register materials are codified once a year in the Code of Federal Regulations and may be obtained at the above address for a cost of: 40 CFR 1-51 thirty seven dollars (\$37.00), 40 CFR 260-299 forty dollars (\$40.00) and 40 CFR 100-149 forty dollars (\$40.00), total one hundred and seventeen dollars (\$117.00).
- (3) The North Carolina Hazardous Waste Management Rules, including the incorporated by reference materials, may be obtained from the Hazardous Waste Section at a cost of sixteen dollars (\$16.00).
- (4) All material is available for inspection at the Department of Environment, Health, and Natural Resources, Hazardous Waste Section, 401 Oberlin Road, Raleigh, N.C.

*Statutory Authority G.S. 130A-294(c).*

#### **.0002 DEFINITIONS**

(a) The definitions contained in G.S. 130A-290 apply to this Subchapter.

(b) 40 CFR 260.10 (Subpart B), Definitions, has been ~~adopted~~ incorporated by reference ~~in accordance with G.S. 150B-14(e), including subsequent amendments and editions~~ except that the Definitions for "Disposal", "Landfill", "Management or hazardous waste management", "Person", "Sludge", "Storage", and "Treatment" are defined by G.S. 130A-290 and are not ~~adopted~~ incorporated by reference.

(c) The following additional definitions shall apply throughout this Subchapter:

- (1) "Section" means the Hazardous Waste

Section, in the Division of Solid Waste Management, Department of Environment, Health, and Natural Resources.

- (2) The "Department" means the N.C. Department of Environment, Health, and Natural Resources (DEHNR).
- (3) "Division" means the Solid Waste Management Division (SWMD).
- (4) "Long Term Storage" means the containment of hazardous waste for an indefinite period of time in a facility designed to be closed with the hazardous waste in place.
- (5) "Off-site Recycling Facility" means any facility that receives shipments of hazardous waste from off-site to be recycled or processed for recycling through any process conducted at the facility.

*Statutory Authority G.S. 130A-294(c).*

#### **.0003 PETITIONS - PART 260**

(a) All rulemaking petitions for changes in this Subchapter shall be made in accordance with 15A NCAC 24B .0001.

(b) 40 CFR 260.21 through 260.41 (Subpart C), "Rulemaking Petitions," have been incorporated ~~adopted~~ by reference ~~in accordance with G.S. 150B-14(e) including subsequent amendments and editions.~~

*Statutory Authority G.S. 130A-294(c).*

#### **.0004 PUBLIC INFORMATION - PART 2**

(a) The provisions concerning requests for information in 40 CFR 2.100 to 2.120 (Subpart A) have been incorporated ~~adopted~~ by reference ~~in accordance with G.S. 150B-14(e) including subsequent amendments and editions~~, except that 40 CFR 2.100 (a) is not ~~adopted~~ incorporated by reference.

- (1) The following shall be substituted for the provisions of 40 CFR 2.100(a) which are not incorporated ~~adopted~~ by reference:
  - (2) Definitions.
    - (A) "EPA" means the United States Environmental Protection Agency.
    - (B) "Department of Environment, Health, and Natural Resources" shall be substituted for "Environmental Protection Agency" and "Hazardous Waste Section Chief in the Solid

Waste Management Division of the Department of Environment, Health, and Natural Resources" shall be substituted for "Administrator", "Regional Administrator" and "Director", except in those situations where authority has not been delegated to the State of N.C. or unless the context requires a different meaning.

- (C) "Section" means the N.C. Hazardous Waste Section, in the Division of Solid Waste Management, Department of Environment, Health, and Natural Resources.
- (D) "Section Officer" means the person designated by the Section Chief to this activity.
- (E) "Section Attorney" means the person designated by the Section Chief to do this activity.
- (F) Section Officer shall be substituted for the freedom of information officer.
- (G) "N.C. Hazardous Waste Section Public Affairs Director" shall be substituted for the EPA Director of the Office of Public Affairs.
- (H) "N.C. Hazardous Waste Section Office" shall be substituted for Regional EPA Office or/EPA Branch Office.
- (I) "Department" means N.C. Department of Environment, Health, and Natural Resources.
- (J) "Section Employee" shall be substituted for EPA Employee.
- (K) "Section Legal Office" shall be the Section Attorney.

(b) The provisions concerning confidentiality of business information in 40 CFR 2.201 to 2.309 (Subpart B) have been incorporated adopted by reference ~~in accordance with G.S. 150B-14(e) including subsequent amendments and editions~~, except that 40 CFR 2.209(b) and (c), 2.301, 2.302, 2.303, 2.304, 2.306, 2.307, 2.308 and 2.309 are not ~~adopted incorporated~~ by reference.

*Statutory Authority G.S. 130A-294(c).*

**.0005 GENERAL PROGRAM REQUIREMENTS - PART 124**

40 CFR 124.1 through 124.21 (Subpart A), "General Program Requirements", have been incorporated adopted by reference ~~in accordance with G.S. 150B-14(e) including subsequent~~

amendments and editions, except that 40 CFR 124.2(c) is not incorporated adopted by reference.

*Statutory Authority G.S. 130A-294(c).*

**.0006 IDENTIFICATION AND LISTING OF HAZARDOUS WASTES - PART 261**

(a) 40 CFR 261.1 through 261.8 (Subpart A), "General", have been incorporated adopted by reference ~~in accordance with G.S. 150B-14(e) including subsequent amendments and editions~~.

(b) 40 CFR 261.10 through 261.11 (Subpart B), "Criteria for Identifying the Characteristics of Hazardous Waste and for Listing Hazardous Waste", have been incorporated adopted by reference ~~in accordance with G.S. 150B-14(e) including subsequent amendments and editions~~.

(c) 40 CFR 261.20 through 261.24 (Subpart C), "Characteristics of Hazardous Waste" have been incorporated adopted by reference including subsequent amendments and editions ~~in accordance with G.S. 150B-14(e)~~.

(d) 40 CFR 261.30 through 261.35 (Subpart D), "Lists of Hazardous Wastes" have been incorporated by reference including subsequent amendments and editions.

(e) The Appendices to 40 CFR Part 261 have been incorporated adopted by reference ~~in accordance with G.S. 150B-14(e) including subsequent amendments and editions~~.

*Statutory Authority G.S. 130A-294(c).*

**.0007 STDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE - PART 262**

(a) 40 CFR 262.10 through 262.12 (Subpart A), "General", have been incorporated adopted by reference ~~in accordance with G.S. 150B-14(e) including subsequent amendments and editions~~.

(b) 40 CFR 262.20 through 262.23 (Subpart B), "The Manifest", have been incorporated adopted by reference including subsequent amendments and editions ~~in accordance with G.S. 150B-14(e)~~.

(c) 40 CFR 262.30 through 262.34 (Subpart C), "Pre-Transport Requirements", have been incorporated adopted by reference ~~in accordance with G.S. 150B-14(e) including subsequent amendments and editions~~.

(d) 40 CFR 262.40 through 262.44 (Subpart D), "Recordkeeping and Reporting", have been incorporated adopted by reference including subsequent amendments and editions ~~in accordance with G.S. 150B-14(e)~~. In addition, a generator

shall keep records of inspections and results of inspections required by Section 262.34 for at least three years from the date of the inspection.

(e) 40 CFR 262.50 through 262.58 (Subpart E), "Exports of Hazardous Waste", have been incorporated ~~adopted~~ by reference including subsequent amendments and editions ~~in accordance with G.S. 150B-14(e).~~

(f) 40 CFR 262.60 (Subpart F), "Imports of Hazardous Waste", has been incorporated ~~adopted~~ by reference including subsequent amendments and editions ~~in accordance with G.S. 150B-14(e).~~

(g) 40 CFR 262.70 (Subpart G), "Farmers" has been incorporated ~~adopted~~ by reference including subsequent amendments and editions ~~in accordance with G.S. 150B-14(e).~~

(h) The Appendix to 40 CFR Part 262 has been incorporated ~~adopted~~ by reference including subsequent amendments and editions ~~in accordance with G.S. 150B-14(e)~~; however, Items D, F, H, and I on the form in the Appendix to 40 CFR Part 262 are required to be completed on the North Carolina Hazardous Waste Manifest form.

*Statutory Authority G.S. 130A-294(c).*

#### **.0008 STDS APPLICABLE TO TRANSPORTERS OF HAZARDOUS WASTE - PART 263**

(a) 40 CFR 263.10 through 263.12 (Subpart A), "General", have been incorporated ~~adopted~~ by reference including subsequent amendments and editions ~~in accordance with G.S. 150B-14(e).~~

(b) 40 CFR 263.20 through 263.22 (Subpart B), "Compliance With the Manifest System and Recordkeeping", have been incorporated ~~adopted~~ by reference including subsequent amendments and editions ~~in accordance with G.S. 150B-14(e).~~

(c) 40 CFR 263.30 through 263.31 (Subpart C), "Hazardous Waste Discharges", have been incorporated ~~adopted~~ by reference including subsequent amendments and editions ~~in accordance with G.S. 150B-14(e).~~

*Statutory Authority G.S. 130A-294(c).*

#### **.0009 STANDARDS FOR OWNERS/OPERATORS OF HWTSD FACILITIES - PART 264**

(a) Any person who treats, stores or disposes of hazardous waste shall comply with the requirements set forth in this Section. The treatment, storage or disposal of hazardous waste is prohibited except as provided in this Section.

(b) 40 CFR 264.1 through 264.4 (Subpart A),

"General", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(c) 40 CFR 264.10 through 264.19 (Subpart B), "General Facility Standards", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(d) 40 CFR 264.30 through 264.37 (Subpart C), "Preparedness and Prevention", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(e) 40 CFR 264.50 through 264.56 (Subpart D), "Contingency Plan and Emergency Procedures", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(f) 40 CFR 264.70 through 264.77 (Subpart E), "Manifest System, Recordkeeping, and Reporting", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(g) 40 CFR 264.90 through 264.101 (Subpart F), "Releases From Solid Waste Management Units", have been incorporated by reference including subsequent amendments and editions ~~additions~~. For the purpose of this incorporation by reference, "January 26, 1983" shall be substituted for "July 26, 1982" contained in 40 CFR 264.90(a)(2).

(h) 40 CFR 264.110 through 264.120 (Subpart G), "Closure and Post-Closure", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(i) 40 CFR 264.140 through 264.151 (Subpart H), "Financial Requirements", have been incorporated by reference including subsequent amendments and editions ~~additions~~, except that 40 CFR 264.143(a)(3), (a)(4), (a)(5), (a)(6), 40 CFR 264.145(a)(3), (a)(4), (a)(5), and 40 CFR 264.151(a)(1), Section 15 are not incorporated by reference.

(1) The following shall be substituted for the provisions of 40 CFR 264.143(a)(3) which were not incorporated by reference:

The owner or operator shall deposit the full amount of the closure cost estimate at the time the fund is established. Within 1 year of the effective date of these Rules ~~regulations~~, an owner or operator using a closure trust fund established prior to the effective date of these Rules ~~regulations~~ shall deposit an amount into the fund so that its value after this deposit at least equals the amount of the current closure cost

estimate, or shall obtain other financial assurance as specified in this Section.

- (2) The following shall be substituted for the provisions of 40 CFR 264.143(a)(6) which were not incorporated by reference:

After the trust fund is established, whenever the current closure cost estimate changes, the owner or operator shall compare the new estimate with the trustee's most recent annual valuation of the trust fund. If the value of the fund is less than the amount of the new estimate, the owner or operator within 60 days after the change in the cost estimate, shall either deposit an amount into the fund so that its value after this deposit at least equals the amount of the current closure cost estimate, or obtain other financial assurance as specified in this section to cover the difference.

- (3) The following shall be substituted for the provisions of 40 CFR 264.145(a)(3) which were not incorporated by reference:

- (A) Except as otherwise provided in Paragraph (i)(3)(B) of this Section, the owner or operator shall deposit the full amount of the post-closure cost estimate at the time the fund is established.

- (B) If the Department finds that the owner or operator of an inactive hazardous waste disposal unit cannot provide financial assurance for post-closure through any other option (e.g. surety bond, letter of credit, or corporate guarantee), a plan for annual payments to the trust fund over the term of the RCRA post-closure permit may be established by the Department as a permit condition.

- (4) The following additional requirement shall apply:

The Trustee shall notify the Department of payment to the trust fund, by certified mail within ten days following said payment to the trust fund. The notice shall contain the name of the Grantor, the date of payment, the amount of payment, and the current value of the trust fund.

- (j) 40 CFR 264.170 through 264.178 (Subpart I), "Use and Management of Containers", have been incorporated by reference' including

subsequent amendments and ~~editions~~ additions.

- (k) 40 CFR 264.190 through 264.199 (Subpart J), "Tank Systems", have been incorporated by reference including subsequent amendments and ~~editions~~ additions.

- (l) The following are requirements for Surface Impoundments:

- (1) 40 CFR 264.220 through 264.231 (Subpart K), "Surface Impoundments", have been incorporated by reference including subsequent amendments and ~~editions~~ additions.

- (2) The following are additional standards for surface impoundments:

- (A) The liner system shall consist of at least two liners;
- (B) Artificial liners shall be equal to or greater than 30 mils in thickness;
- (C) Clayey liners shall be equal to or greater than five feet in thickness and have a maximum permeability of  $1.0 \times 10^{-7}$  cm/sec;
- (D) Clayey liner soils shall have the same characteristics as described in (r)(4)(B)(ii), (iii), (iv), (vi) and (vii) of this Rule;
- (E) A leachate collection system shall be constructed between the upper liner and the bottom liner;
- (F) A leachate detection system shall be constructed below the bottom liner; and
- (G) Surface impoundments shall be constructed in such a manner to prevent landsliding, slippage or slumping.

- (m) 40 CFR 264.250 through 264.259 (Subpart L), "Waste Piles", have been incorporated by reference including subsequent amendments and ~~editions~~ additions.

- (n) 40 CFR 264.270 through 264.283 (Subpart M), "Land Treatment", have been incorporated by reference including subsequent amendments and ~~editions~~ additions.

- (o) 40 CFR 264.300 through 264.317 (Subpart N), "Landfills", have been incorporated by reference including subsequent amendments and ~~editions~~ additions.

- (p) A long-term storage facility shall meet groundwater protection, closure and post-closure, and financial requirements for disposal facilities as specified in Paragraphs (g), (h), and (i) of this Rule.

- (q) 40 CFR 264.340 through 264.351 (Subpart O), "Incinerators", have been incorporated by

reference including subsequent amendments and ~~editions~~ additions.

(r) The following are additional location standards for facilities:

- (1) In addition to the location standards set forth in 15A NCAC 13A .0009(c), the Department, in determining whether to issue a permit for a hazardous waste management facility, shall consider the risks posed by the proximity of the facility to water table levels, flood plains, water supplies, public water supply watersheds, mines, natural resources such as wetlands, endangered species habitats, parks, forests, wilderness areas, and historical sites, and population centers and shall consider whether provision has been made for adequate buffer zones. The Department shall also consider ground water travel time, soil pH, soil cation exchange capacity, soil composition and permeability, slope, climate, local land use, transportation factors such as proximity to waste generators, route, route safety, and method of transportation, aesthetic factors such as the visibility, appearance, and noise level of the facility; potential impact on air quality, existence of seismic activity and cavernous bedrock.

- (2) The following minimum separation distances shall be required of all hazardous waste management facilities except that existing facilities shall be required to meet these minimum separation distances to the maximum extent feasible:

- (A) All hazardous waste management facilities shall be located at least 0.25 miles from institutions including but not limited to schools, health care facilities and prisons, unless the owner or operator can demonstrate that no unreasonable risks shall be posed by the proximity of the facility.
- (B) All hazardous waste treatment and storage facilities shall comply with the following separation distances: all hazardous waste shall be treated and stored a minimum of 50 feet from the property line of the facility; except that all hazardous waste with ignitable, incompatible or reactive characteristics shall be treated and

stored a minimum of 200 feet from the property line of the facility if the area adjacent to the facility is zoned for any use other than industrial or is not zoned.

- (C) All hazardous waste landfills, long-term storage facilities, land treatment facilities and surface impoundments, shall comply with the following separation distances:

- (i) All hazardous waste shall be located a minimum of 200 feet from the property line of the facility;
- (ii) Each hazardous waste landfill, long-term storage or surface impoundment facility shall be constructed so that the bottom of the facility is 10 feet or more above the historical high ground water level. The historical high ground water level shall be determined by measuring the seasonal high ground water levels and predicting the long-term maximum high ground water level from published data on similar North Carolina topographic positions, elevations, geology, and climate; and
- (iii) All hazardous waste shall be located a minimum of 1,000 feet from the zone of influence of any existing off-site ground water well used for drinking water, and outside the zone of influence of any existing or planned on-site drinking water well.

- (D) Hazardous waste storage and treatment facilities for liquid waste that is classified as TC toxic, toxic, or acutely toxic and is stored or treated in tanks or containers shall not be located:

- (i) in the recharge area of an aquifer which is designated as an existing sole drinking water source as defined in the Safe Drinking Water Act, Section .1424(e) [42 U.S.C. 300h-3(e)] unless an adequate secondary containment system is constructed, and after consideration of applicable factors in (r)(3) of this Rule, the owner or operator can demonstrate no



- (ii) unreasonable risk to public health; within 200 feet of surface water impoundments or surface water stream with continuous flow as defined by the United States Geological Survey;
  - (iii) in an area that will allow direct surface or subsurface discharge to WS-I, WS-II or SA waters or a Class III Reservoir as defined in 15A NCAC 2B .0200 and 15A NCAC 18C .0102;
  - (iv) in an area that will allow direct surface or subsurface discharge to the watershed for a Class I or II Reservoir as defined in 15A NCAC 18C .0102;
  - (v) within 200 feet horizontally of a 100-year floodplain elevation;
  - (vi) within 200 feet of a seismically active area as defined in (c) of this Rule; and
  - (vii) within 200 feet of a mine, cave, or cavernous bedrock.
- (3) The Department may require any hazardous waste management facility to comply with greater separation distances or other protective measures necessary to avoid unreasonable risks posed by the proximity of the facility to water table levels, flood plains, water supplies, public water supply watersheds, mines, natural resources such as wetlands, endangered species habitats, parks, forests, wilderness areas, and historical sites, and population centers or to provide an adequate buffer zone. The Department may also require protective measures necessary to avoid unreasonable risks posed by the soil pH, soil cation exchange capacity, soil composition and permeability, climate, transportation factors such as proximity to waste generators, route, route safety, and method of transportation, aesthetic factors such as the visibility, appearance, and noise level of the facility, potential impact on air quality, and the existence of seismic activity and cavernous bedrock. In determining whether to require greater separation distances or other protective measures, the Department shall consider the following factors:
  - (A) All proposed hazardous waste activities and procedures to be associated with the transfer, storage, treatment or disposal of hazardous waste at the facility;
  - (B) The type of hazardous waste to be treated, stored, or disposed of at the facility;
  - (C) The volume of waste to be treated, stored, or disposed of at the facility;
  - (D) Land use issues including the number of permanent residents in proximity to the facility and their distance from the facility;
  - (E) The adequacy of facility design and plans for containment and control of sudden and non-sudden accidental events in combination with adequate off-site evacuation of potentially adversely impacted populations;
  - (F) Other land use issues including the number of institutional and commercial structures such as airports and schools in proximity to the facility, their distance from the facility, and the particular nature of the activities that take place in those structures;
  - (G) The lateral distance and slope from the facility to surface water supplies or to watersheds draining directly into surface water supplies;
  - (H) The vertical distance, and type of soils and geologic conditions separating the facility from the water table;
  - (I) The direction and rate of flow of ground water from the sites and the extent and reliability of on-site and nearby data concerning seasonal and long-term groundwater level fluctuations;
  - (J) Potential air emissions including rate, direction of movement, dispersion and exposure, whether from planned or accidental, uncontrolled releases; and
  - (K) Any other relevant factors.
- (4) The following are additional location standards for landfills, long-term storage facilities and hazardous waste surface impoundments:
  - (A) A hazardous waste landfill, long-term storage, or a surface impoundment facility shall not be located:
    - (i) In the recharge area of an aquifer

- which is an existing sole drinking water source;
- (ii) Within 200 feet of a surface water stream with continuous flow as defined by the United States Geological Survey;
  - (iii) In an area that will allow direct surface or subsurface discharge to WS-I, WS-II or SA waters or Class III Reservoir as defined in 15A NCAC 2B .0200 and 15A NCAC 18C .0102;
  - (iv) In an area that will allow direct surface or subsurface discharge to a watershed for a Class I or II Reservoir as defined in 15A NCAC 18C .0102;
  - (v) Within 200 feet horizontally of a 100-year flood hazard elevation;
  - (vi) Within 200 feet of a seismically active area as defined in (c) of this Rule; and
  - (vii) Within 200 feet of a mine, cave or cavernous bedrock.
- (B) A hazardous waste landfill or long-term storage facility shall be located in highly weathered, relatively impermeable clayey formations with the following soil characteristics:
- (i) The depth of the unconsolidated soil materials shall be equal to or greater than 20 feet;
  - (ii) The percentage of fine-grained soil material shall be equal to or greater than 30 percent passing through a number 200 sieve;
  - (iii) Soil liquid limit shall be equal to or greater than 30;
  - (iv) Soil plasticity index shall be equal to or greater than 15;
  - (v) Soil compacted hydraulic conductivity shall be a maximum of  $1.0 \times 10^{-7}$  cm/sec;
  - (vi) Soil Cation Exchange Capacity shall be equal to or greater than 5 milliequivalents per 100 grams;
  - (vii) Soil Potential Volume Change Index shall be equal to or less than 4; and
  - (viii) Soils shall be underlain by a competent geologic formation having a rock quality designation equal to or greater than 75 percent unless other geological conditions afford adequate protection of public health and the environment.
- (C) A hazardous waste landfill or long-term storage facility shall be located in areas of low to moderate relief to the extent necessary to prevent landsliding or slippage and slumping. The site may be graded to comply with this standard.
- (5) All new hazardous waste impoundments that close with hazardous waste residues left in place shall comply with the standards for hazardous waste landfills in (r)(4) of this Rule unless the applicant can demonstrate that equivalent protection of public health and environment is afforded by some other standard.
  - (6) The owners and operators of all new hazardous waste management facilities shall construct and maintain a minimum of two observation wells, one upgradient and one downgradient of the proposed facility; and shall establish background groundwater concentrations and monitor annually for all hazardous wastes that the owner or operator proposes to store, treat, or dispose at the facility.
  - (7) The owners and operators of all new hazardous waste facilities shall demonstrate that the community has had an opportunity to participate in the siting process by complying with the following:
    - (A) The owners and operators shall hold at least one public meeting in the county in which the facility is to be located to inform the community of all hazardous waste management activities including but not limited to: the hazardous properties of the waste to be managed; the type of management proposed for the wastes; the mass and volume of the wastes; and the source of the wastes; and to allow the community to identify specific health, safety and environmental concerns or problems expressed by the community related to the hazardous waste activities associated with the facility. The owners and operators shall provide a public notice of this meeting at least 30 days prior to the meeting. Public

notice shall be documented in the facility permit application. The owners and operators shall submit as part of the permit application a complete written transcript of the meeting, all written material submitted that represents community concerns, and all other relevant written material distributed or used at the meeting. The written transcript and other written material submitted or used at the meeting shall be submitted to the local public library closest to and in the county of the proposed site with a request that the information be made available to the public.

- (B) For the purposes of this Rule, public notice shall include: notification of the boards of county commissioners of the county where the proposed site is to be located and all contiguous counties in North Carolina; a legal advertisement placed in a newspaper or newspapers serving those counties; and provision of a news release to at least one newspaper, one radio station, and one TV station serving these counties. Public notice shall include the time, place, and purpose of the meetings required by this Rule.
- (C) No less than 30 days after the first public meeting transcript is available at the local public library, the owners and operators shall hold at least one additional public meeting in order to attempt to resolve community concerns. The owners and operators shall provide public notice of this meeting at least 30 days prior to the meeting. Public notice shall be documented in the facility permit application. The owners and operators shall submit as part of the permit application a complete written transcript of the meeting, all written material submitted that represents community concerns, and all other relevant written material distributed or used at the meeting.
- (D) The application, written transcripts of all public meetings and any additional material submitted or used at the meetings, and any additions or corrections to the application,

including any responses to notices of deficiencies shall be submitted to the local library closest to and in the county of the proposed site, with a request that the information be made available to the public until the permit decision is made.

- (E) The Department shall consider unresolved community concerns in the permit review process and impose final permit conditions based on sound scientific, health, safety, and environmental principles as authorized by applicable laws or rules.

(s) 40 CFR 264.570 through 264.575 (Subpart W), "Drip Pads", have been incorporated by reference including subsequent amendments and editions.

(t) 40 CFR 264.600 through 264.603 (Subpart X), "Miscellaneous Units", have been incorporated by reference including subsequent amendments and editions.

(u) 40 CFR 264.1030 through 264.1049 (Subpart AA), "Air Emission Standards for Process Vents", have been incorporated by reference including subsequent amendments and editions.

(v) 40 CFR 264.1050 through 264.1079 (Subpart BB), "Air Emission Standards for Equipment Leaks", have been incorporated by reference including subsequent amendments and editions.

(w) 40 CFR 264.1100 through 264.1102 (Subpart DD), "Containment Buildings", have been incorporated by reference including subsequent amendments and editions.

(x) ~~(w)~~ Appendices to 40 CFR Part 264 have been incorporated by reference including subsequent amendments and editions.

*Statutory Authority G.S. 130A-294(c).*

#### **.0010 INTERIM STATUS STDS FOR OWNERS-OP OF HWTSD FACILITIES - PART 265**

(a) 40 CFR 265.1 through 265.4 (Subpart A), "General", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(b) 40 CFR 265.10 through 265.19 (Subpart B), "General Facility Standards", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(c) 40 CFR 265.30 through 265.37 (Subpart C), "Preparedness and Prevention", have been

incorporated by reference including subsequent amendments and editions ~~additions~~.

(d) 40 CFR 265.50 through 265.56 (Subpart D), "Contingency Plan and Emergency Procedures", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(e) 40 CFR 265.70 through 265.77 (Subpart E), "Manifest System, Recordkeeping, and Reporting", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(f) 40 CFR 265.90 through 265.94 (Subpart F), "Ground-Water Monitoring", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(g) 40 CFR 265.110 through 265.120 (Subpart G), "Closure and Post-Closure", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(h) 40 CFR 265.140 through 265.151 (Subpart H), "Financial Requirements", have been incorporated by reference including subsequent amendments and editions ~~additions~~, except that 40 CFR 265.143(a)(3), (a)(4), (a)(5), (a)(6), and 40 CFR 265.145(a)(3), (a)(4), (a)(5), are not incorporated by reference.

- (1) The following shall be substituted for the provisions of 40 CFR 265.143(a)(3) which were not incorporated by reference:

The owner or operator shall deposit the full amount of the closure cost estimate at the time the fund is established. Within 1 year of the effective date of these Rules ~~regulations~~, an owner or operator using a closure trust fund established prior to the effective date of these Rules ~~regulations~~ shall deposit an amount into the fund so that its value after this deposit at least equals the amount of the current closure cost estimate, or shall obtain other financial assurance as specified in this Section.

- (2) The following shall be substituted for the provisions of 40 CFR 265.143(a)(6) which were not incorporated by reference:

After the trust fund is established, whenever the current closure cost estimate changes, the owner or operator shall compare the new estimate with the trustee's most recent annual valuation of the trust fund. If the value of the fund is less than the amount of the new estimate, the owner or operator within

60 days after the change in the cost estimate, shall either deposit an amount into the fund so that its value after this deposit at least equals the amount of the current closure cost estimate, or obtain other financial assurance as specified in this Section to cover the difference.

- (3) The following shall be substituted for the provisions of 40 CFR 265.145(a)(3) which were not incorporated by reference:

(A) Except as otherwise provided in Paragraph (h)(3)(B) of this Section, the owner or operator shall deposit the full amount of the post-closure cost estimate at the time the fund is established.

(B) If the Department finds that the owner or operator of an inactive hazardous waste disposal unit cannot provide financial assurance for post-closure through any other option (e.g. surety bond, letter of credit, or corporate guarantee), a plan for annual payments to the trust fund during the interim status period may be established by the Department by use of an Administrative Order.

(i) 40 CFR 265.170 through 265.177 (Subpart I), "Use and Management of Containers", have been incorporated by reference including subsequent amendments and editions ~~additions~~. Additionally, the owner or operator shall keep records and results of required inspections for at least three years from the date of the inspection.

(j) 40 CFR 265.190 through 265.201 (Subpart J), "Tank Systems", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(k) 40 CFR 265.220 through 265.230 (Subpart K), "Surface Impoundments", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(l) 40 CFR 265.250 through 265.260 (Subpart L), "Waste Piles", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(m) 40 CFR 265.270 through 265.282 (Subpart M), "Land Treatment", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(n) 40 CFR 265.300 through 265.316 (Subpart N), "Landfills", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(o) 40 CFR 265.340 through 265.352 (Subpart O), "Incinerators", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(p) 40 CFR 265.370 through 265.383 (Subpart P), "Thermal Treatment", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(q) 40 CFR 265.400 through 265.406 (Subpart Q), "Chemical, Physical, and Biological Treatment", have been incorporated by reference including subsequent amendments and editions ~~additions~~.

(r) 40 CFR 265.440 through 265.445 (Subpart W), "Drip Pads", have been incorporated by reference including subsequent amendments and editions.

(s) 40 CFR 265.1030 through 265.1049 (Subpart AA), "Air Emission Standards for Process Vents", have been incorporated by reference including subsequent amendments and editions.

(t) 40 CFR 265.1050 through 265.1079 (Subpart BB), "Air Emission Standards for Equipment Leaks", have been incorporated by reference including subsequent amendments and editions.

(u) 40 CFR 265.1100 through 265.1102 (Subpart DD), "Containment Buildings", have been incorporated by reference including subsequent amendments and editions.

(v) ~~(u)~~ Appendices to 40 CFR Part 265 have been incorporated by reference including subsequent amendments and editions.

*Statutory Authority G.S. 130A-294(c).*

**.0011 STDS FOR THE MGMT OF SPECIFIC HW/TYPES HWM FACILITIES - PART 266**

(a) 40 CFR 266.20 through 266.23 (Subpart C), "Recyclable Materials Used in a Manner Constituting Disposal", have been incorporated by reference in accordance with G.S. 150B-14(e) including subsequent amendments and editions.

(b) 40 CFR 266.30 through 266.35 (Subpart D), "Hazardous Waste Burned for Energy Recovery", have been incorporated by reference in accordance with G.S. 150B-14(e) including subsequent amendments and editions.

(c) 40 CFR 266.40 through 266.44 (Subpart E), "Used Oil Burned for Energy Recovery", have been incorporated by reference in accordance with G.S. 150B-14(e) including subsequent amendments and editions.

(d) 40 CFR 266.70 (Subpart F), "Recyclable

Materials Utilized for Precious Metal Recovery", has been incorporated by reference in accordance with G.S. 150B-14(e) including subsequent amendments and editions.

(e) 40 CFR 266.80 (Subpart G), "Spent Lead-Acid Batteries Being Reclaimed", has been incorporated by reference in accordance with G.S. 150B-14(e) including subsequent amendments and editions.

(f) 40 CFR 266.100 through 266.122 (Subpart H), "Hazardous Waste Burned in Boilers and Industrial Furnaces", have been incorporated by reference in accordance with G.S. 150B-14(e) including subsequent amendments and editions.

(g) Appendices to 40 CFR Part 266 have been incorporated by reference in accordance with G.S. 150B-14(e) including subsequent amendments and editions.

*Statutory Authority G.S. 130A-294(c).*

**.0012 LAND DISPOSAL RESTRICTIONS - PART 268**

(a) 40 CFR 268.1 through 268.14 ~~268.13~~ (Subpart A), "General", have been incorporated by reference in accordance with G.S. 150B-14(e) including subsequent amendments and editions.

(b) 40 CFR 268.30 through 268.36 ~~268.35~~ (Subpart C), "Prohibitions on Land Disposal", have been incorporated ~~adopted~~ by reference including subsequent amendments and editions in accordance with G.S. 150B-14(e).

(c) 40 CFR 268.40 through 268.46 ~~268.44~~ (Subpart D), "Treatment Standards", have been incorporated ~~adopted~~ by reference in accordance with G.S. 150B-14(e) including subsequent amendments and editions.

(d) 40 CFR 268.50 (Subpart E), "Prohibitions on Storage", has been incorporated ~~adopted~~ by reference in accordance with G.S. 150B-14(e) including subsequent amendments and editions.

(e) Appendices to 40 CFR Part 268 have been incorporated ~~adopted~~ by reference in accordance with G.S. 150B-14(e) including subsequent amendments and editions.

*Statutory Authority G.S. 130A-294(c).*

**.0013 THE HAZARDOUS WASTE PERMIT PROGRAM - PART 270**

(a) 40 CFR 270.1 through 270.6 (Subpart A), "General Information", have been incorporated by reference in accordance with G.S.

~~+50B-14(e)~~ including subsequent amendments and editions. For the purpose of this ~~adoption~~ incorporation by reference, "January 26, 1983" shall be substituted for "July 26, 1982" contained in 40 CFR ~~264.90(a)~~ 270.1(c).

(b) 40 CFR 270.10 through 270.29 (Subpart B), "Permit Application", have been ~~adopted~~ incorporated by reference in accordance with G.S. ~~+50B-14(e)~~ including subsequent amendments and editions.

(c) The following are additional Part B information requirements for all hazardous waste treatment, storage or disposal facilities:

- (1) Description and documentation of the public meetings as required in 15A NCAC 13A .0009 (r)(7);
- (2) A description of the hydrological and geological properties of the site including, at a minimum, flood plains, depth to water table, ground water travel time, seasonal and long-term groundwater level fluctuations, proximity to public water supply watersheds, consolidated rock, soil pH, soil cation exchange capacity, soil characteristics and composition and permeability, existence of cavernous bedrock and seismic activity, slope, mines, climate, location and withdrawal rates of surface water users within the immediate drainage basin and well water users within a one mile radius of the facility; water quality information of both surface and groundwater within 1000 ft. of the facility, and a description of the local air quality;
- (3) A description of the facility's proximity to and potential impact on wetlands, endangered species habitats, parks, forests, wilderness areas, historical sites, mines, and air quality;
- (4) A description of local land use including residential, industrial, commercial, recreational, agricultural and the proximity to schools and airports;
- (5) A description of the proximity of the facility to waste generators and population centers; a description of the method of waste transportation; the comments of the local community and state transportation authority on the proposed route, and route safety. Comments should include proposed alternative routes and restrictions

necessary to protect the public health;

- (6) A description of facility aesthetic factors including visibility, appearance, and noise level; and
- (7) A description of any other objective factors that the Department determines are reasonably related and relevant to the proper siting and operation of the facility.

(d) In addition to the specific ~~Specific~~ Part B information requirements ~~Information Requirements~~ for hazardous waste disposal facilities, owners and operators of hazardous waste landfills or longterm storage facilities shall provide the following information:

- (1) Design drawings and specifications of the leachate collection and removal system;
- (2) Design drawings and specifications of the artificial impervious liner;
- (3) Design drawings and specifications of the clay or clay-like liner below the artificial liner, and a description of the permeability of the clay or clay-like liner; and
- (4) A description of how hazardous wastes will be treated prior to placement in the facility.

(e) In addition to the specific Part B ~~Information~~ information requirements for surface impoundments ~~Surface Impoundments~~, owners and operators of surface impoundments shall provide the following information:

- (1) Design drawings and specifications of the leachate collection and removal system;
- (2) Design drawings and specifications of all artificial impervious liners;
- (3) Design drawings and specifications of all clay or clay-like liners and a description of the clay or clay-like liner; and
- (4) Design drawings and specifications that show that the facility has been constructed in a manner that will prevent landsliding, slippage, or slumping.

(f) 40 CFR 270.30 through 270.33 (Subpart C), "Permit Conditions", have been ~~adopted~~ incorporated by reference in accordance with G.S. ~~+50B-14(e)~~ including subsequent amendments and editions.

(g) 40 CFR 270.40 through 270.43 (Subpart D), "Changes to Permit", have been ~~adopted~~ incorporated by reference in accordance with G.S.

~~150B-14(e) including subsequent amendments and editions.~~

(h) 40 CFR 270.50 through 270.51 (Subpart E), "Expiration and Continuation of Permits", have been ~~adopted~~ incorporated by reference in ~~accordance with G.S. 150B-14(e) including subsequent amendments and editions.~~

(i) 40 CFR 270.60 through 270.66 (Subpart F), "Special Forms of Permits", have been ~~adopted~~ incorporated by reference in ~~accordance with G.S. 150B-14(e) including subsequent amendments and editions.~~

(j) 40 CFR 270.70 through 270.73 (Subpart G), "Interim Status", have been ~~adopted~~ incorporated by reference in ~~accordance with G.S. 150B-14(e) including subsequent amendments and editions.~~ For the purpose of this ~~adoption~~ incorporation by reference, "January 1, 1986" shall be substituted for "November 8, 1985" contained in 40 CFR 270.73(c).

(k) The following are additional permitting requirements concerning operating record of other facilities.

(1) An applicant applying for a permit for a hazardous waste facility shall submit a disclosure statement to the Department as a part of the application for a permit or any time thereafter specified by the Department. The disclosure statement shall be supported by an affidavit attesting to the truth and completeness of the facts asserted in the statement and shall include:

- (A) A brief description of the form of the business (e.g. partnership, sole proprietorship, corporation, association, or other);
- (B) The name and address of any hazardous waste facility constructed or operated after October 21, 1976, by the applicant or any parent or subsidiary corporation if the applicant is a corporation; and
- (C) A list identifying any legal action taken against any facility identified in Part (k)(1)(B) of this Rule involving:
  - (i) any administrative ruling or order issued by any state, federal or local authority relating to revocation of any environmental or waste management permit or license, or to a violation of any state or federal statute or local ordinance relating to waste management or environmental

protection;

- (ii) any judicial determination of liability or conviction under any state or federal law or local ordinance relating to waste management or environmental protection; and
- (iii) any pending administrative or judicial proceeding of the type described in this Part.

(D) The identification of each action described in Part (k)(1)(C) of this Rule shall include the name and location of the facility that the action concerns, the agency or court that heard or is hearing the matter, the title, docket or case number, and the status of the proceeding.

(2) In addition to the information set forth in Subparagraph (k)(1) of this Rule, the Department may require from any applicant such additional information as it deems necessary to satisfy the requirements of G.S. 130A-295. Such information may include, but shall not be limited to:

- (A) The names, addresses, and titles of all officers, directors, or partners of the applicant and of any parent or subsidiary corporation if the applicant is a corporation;
- (B) The name and address of any company in the field of hazardous waste management in which the applicant business or any of its officers, directors, or partners, hold an equity interest and the name of the officer, director, or partner holding such interest; and
- (C) A copy of any administrative ruling or order and of any judicial determination of liability or conviction described in Part (k)(1)(C) of this Rule, and a description of any pending administrative or judicial proceeding in that item.

(3) If the Department finds that any part or parts of the disclosure statement is not necessary to satisfy the requirements of G.S. 130A-295, such information shall not be required.

(1) An applicant for a new, or modification to an existing, commercial facility permit, shall provide a description and justification of the need for the facility.

(m) Requirements for Off-site Recycling Facilities.

- (1) The permit requirements of this Rule apply to owners and operators of off-site recycling facilities.
- (2) The following provisions of 40 CFR Part 264, as incorporated by reference, shall apply to owners and operators of off-site recycling facilities:
  - (A) Subpart B - General Facility Standards
  - (B) Subpart C - Preparedness and Prevention
  - (C) Subpart D - Contingency Plan and Emergency Procedures
  - (D) Subpart E - Manifest System, Record-keeping and Reporting
  - (E) Subpart G - Closure and Post-closure
  - (F) Subpart H - Financial Requirements
  - (G) Subpart I - Use and Management of Containers
  - (H) Subpart J - Tank Systems
  - (I) 264.101 - Corrective Action for Solid Waste Management Units.
  - (J) Subpart X - Miscellaneous Units
  - (K) Subpart DD - Containment Buildings
- (3) The requirements listed in Subparagraph (m)(2) of this Rule apply to the entire off-site recycling facility, including all recycling units, staging and process areas, and permanent and temporary storage areas for recycled products and wastes.
- (4) The following provisions of 15A NCAC 13A .0009 shall apply to owners and operators of off-site recycling facilities:
  - (A) The substitute financial requirements of Rule .0009 (i)(1), (2) and (4).
  - (B) The additional standards of Rule .0009 (r)(1), (2), (3), (6) and (7).
- (5) The owner or operator of an off-site recycling facility shall keep a written operating record at his facility.
- (6) The following information must be recorded, as it becomes available, and maintained in the operating record until closure of the facility:
  - (A) A description and the quantity of each hazardous waste received, and the method(s) and date(s) of its treatment, storage, or recycling at the facility.
  - (B) The location of all hazardous waste within the facility and the quantity at each location. This information must

include cross-references to specific manifest document numbers if the waste was accompanied by a manifest.

- (C) A complete documentation of the fate of all hazardous wastes received from off-site or generated on-site. This shall include records of the sale, reuse, off-site transfer, or disposal of all products and waste materials.

(n) Permit Fees for Commercial Hazardous Waste Facilities

- (1) An applicant for a permit modification for a commercial hazardous waste facility shall pay an application fee as follows:

- (A) Class 1 permit modification \$100
- (B) Class 2 permit modification \$1,000
- (C) Class 3 permit modification \$5,000

{Note: Administrative or informational changes such as personnel or telephone numbers are excluded from the fee requirement.}

- (2) The application fee for a new permit, permit renewal, or permit modification must accompany the application, and is non-refundable. The application shall be considered incomplete until the fee is paid. Checks should be made payable to: Division of Solid Waste Management.

*Statutory Authority G.S. 130A-294(c); 130A-294.1; 130A-295(a)(1), (2), (c).*

**.0014 REQMENTS/AUTHORIZATION OF STATE HAZARDOUS WASTE PROG - PART 271**

40 CFR 271.17, "Sharing of information", has been incorporated adopted by reference ~~in accordance with G.S. 150B-14(e)~~ including subsequent amendments and editions.

*Statutory Authority G.S. 130A-294(c).*

**.0018 STANDARDS FOR THE MANAGEMENT OF USED OIL**

(a) 40 CFR 279.1 (Subpart A), "Definitions", has been incorporated by reference including subsequent amendments and editions.

(b) 40 CFR 279.10 through 279.12 (Subpart B), "Applicability", have been incorporated by reference including subsequent amendments and editions.

(c) 40 CFR 279.20 through 279.24 (Subpart C), "Standards for Used Oil Generators", have been incorporated by reference including subsequent



amendments and editions.

(d) 40 CFR 279.30 through 279.32 (Subpart D), "Standards for Used Oil Collection Centers and Aggregation Points", have been incorporated by reference including subsequent amendments and editions.

(e) 40 CFR 279.40 through 279.47 (Subpart E), "Standards for Used Oil Transporter and Transfer Facilities", have been incorporated by reference including subsequent amendments and editions.

(f) 40 CFR 279.50 through 279.59 (Subpart F), "Standards for Used Oil Processors and Re-Refiners", have been incorporated by reference including subsequent amendments and editions.

(g) 40 CFR 279.60 through 279.67 (Subpart G), "Standards for Used Oil Burners Who Burn Off-Specification Used Oil for Energy Recovery", have been incorporated by reference including subsequent amendments and editions.

(h) 40 CFR 279.70 through 279.75 (Subpart H), "Standards for Used Oil Fuel Marketers", have been incorporated by reference including subsequent amendments and editions.

(i) 40 CFR 279.80 through 279.82 (Subpart I), "Standards for Use as a Dust Suppressant and Disposal of Used Oil" have been incorporated by reference including subsequent amendments and editions.

Statutory Authority G.S. 130A-294(c).

\*\*\*\*\*

*Notice* is hereby given in accordance with G.S. 150B-21.2 that the EHNR-Commission for Health Services intends to amend rules cited as 15A NCAC 13B .01201, .1203, .1207.

*The proposed effective date of this action is April 1, 1993.*

*The public hearing will be conducted at 1:30 p.m. on January 20, 1993 at the Highway Building, First Floor Auditorium, 1 South Wilmington Street, Raleigh, North Carolina.*

*Reason for Proposed Action:* To designate microwave treatment as suitable technology for treating microbiological waste.

*Comment Procedures:* All persons interested in these matters are invited to attend the public

hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629, (919)733-4618. If you desire to speak at the public hearing, notify John P. Barkley at least 3 days prior to the public hearing. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or address proposed changes from staff pursuant to comments made during the public hearing process.

IT IS VERY IMPORTANT THAT ALL INTERESTED AND POTENTIALLY AFFECTED PERSONS, GROUPS, BUSINESSES, ASSOCIATIONS, INSTITUTIONS, OR AGENCIES MAKE THEIR VIEWS AND OPINIONS KNOWN TO THE COMMISSION FOR HEALTH SERVICES THROUGH THE PUBLIC HEARING AND COMMENT PROCESS, WHETHER THEY SUPPORT OR OPPOSE ANY OR ALL PROVISIONS OF THE PROPOSED RULES. THE COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).

## CHAPTER 13 - SOLID WASTE MANAGEMENT

### SUBCHAPTER 13B - SOLID WASTE MANAGEMENT

#### SECTION .1200 - MEDICAL WASTE MANAGEMENT

##### .1201 DEFINITIONS

For the purpose of the Section, the following definitions apply:

- (1) "Blood and body fluids" means liquid blood, serum, plasma, other blood products, emulsified human tissue, spinal fluids, and pleural and peritoneal fluids. Dialysates are not blood or body fluids under this definition.
- (2) "Generating facility" means any facility where medical waste first becomes a waste, including but not limited to any medical or dental facility, funeral home, laboratory, veterinary hospital and blood bank.

- (3) "Integrated medical facility" means one or more health service facilities as defined in NCGS G.S. 131E-176(9b) that are:
  - (a) located in a single county or two contiguous counties;
  - (b) affiliated with a university medical school or that are under common ownership and control; and
  - (c) serve a single service area.
- (4) "Medical waste" as defined in G.S. 130A-290.18 130A-290(18).
- (5) "Microbiological waste" means cultures and stocks of infectious agents, including but not limited to specimens from medical, pathological, pharmaceutical, research, commercial, and industrial laboratories.
- (6) "Microwave treatment" means treatment by microwave energy for sufficient time to render waste non-infectious.
- ~~(6)~~ (7) "Off-site" means any site which is not "on-site".
- ~~(7)~~ (8) "On-site" means the same or geographically contiguous property which may be divided by public or private right-of-way.
- ~~(8)~~ (9) "Pathological waste" means human tissues, organs and body parts; and the carcasses and body parts of all animals that were known to have been exposed to pathogens that are potentially dangerous to humans during research, were used in the production of biologicals or in vivo testing of pharmaceuticals, or that died with a known or suspected disease transmissible to humans.
- ~~(9)~~ (10) "Regulated Medical Waste" means blood and body fluids in individual containers in volumes greater than 20 ml, microbiological waste, and pathological waste that have not been treated pursuant to Rule .1207 of this Section.
- ~~(10)~~ (11) "Sharps" means and includes needles, syringes with attached needles, capillary tubes, slides and cover slips, and scalpel blades.
- ~~(11)~~ (12) "Treatment" as defined in G.S. 130A-309.26(a)(2).

*Statutory Authority G.S. 130A-309.26.*

#### **.1203 GENERAL REQUIREMENTS FOR REGULATED MEDICAL WASTE**

- (a) Regulated medical waste shall be treated

prior to disposal. Acceptable methods of treatment are as follows:

- (1) blood and body fluids in individual containers in volumes greater than 20 ml - Incineration or sanitary sewage systems, provided the sewage treatment authority is notified;
  - (2) microbiological waste - Incineration, steam sterilization, microwave treatment, or chemical treatment;
  - (3) pathological wastes - Incineration.
- (b) Other methods of treatment shall require approval by the Division.
  - (c) Regulated medical waste treated in accordance with Paragraph (a) of this Rule may be managed in accordance with 15A NCAC 13B .0100 - .0700.
  - (d) Crematoriums are not subject to the requirements of Rule .1207(3) of this Section.
  - (e) A person who treats Regulated medical waste at the generating facility or within an integrated medical facility is not subject to the storage and record keeping requirements of Rule .1207(1) of this Section.
  - (f) Generating facilities and integrated medical facilities in operation on October 1, 1990 that incinerate Regulated medical waste are not subject to the requirements of Rule .1207(3)(a-l) of this Section until January 1, 1995.

*Statutory Authority G.S. 130A-309.26.*

#### **.1207 OPERATIONAL REQ/REGULATED MEDICAL WASTE TREATMENT FACILITIES**

A person who treats Regulated medical waste shall meet the following requirements for each type of treatment in addition to the requirements in Rule .1203 of this Section.

- (1) General requirements:
  - (a) Refrigeration at an ambient temperature between 35 and 45 degrees Fahrenheit shall be maintained for Regulated medical waste not treated within seven calendar days after shipment.
  - (b) Regulated medical waste shall be stored prior to treatment for no more than seven calendar days after receipt.
  - (c) Regulated medical waste shall be stored no longer than seven calendar days after treatment.
  - (d) Only authorized personnel shall have access to areas used to store Regulated medical waste.
  - (e) All areas used to store Regulated

- medical waste shall be kept clean. Neither carpets nor floor coverings with seams shall be used in storage areas. Vermin and insects shall be controlled.
- (f) Prior to treatment, all Regulated medical waste shall be confined to the storage area.
  - (g) All floor drains shall discharge directly to an approved sanitary sewage system. Ventilation shall be provided and shall discharge so as not to create nuisance odors.
  - (h) A plan shall be prepared, maintained and updated as necessary to ensure continued proper management of Regulated medical waste at the facility.
  - (i) Records of Regulated medical waste shall be maintained for each shipment and shall include the information listed in this Paragraph. This information shall be maintained at the treatment facility for no less than three years.
    - (i) name and address of generator;
    - (ii) date received;
    - (iii) amount of waste received by number of packages (piece count) from each generator;
    - (iv) date treated;
    - (v) name and address of ultimate disposal facility.
  - (j) Regulated medical waste treatment facilities that treat waste generated off-site shall submit to the Division an annual report, by March 1 of each year that summarizes the information collected under ~~Subparagraph~~ Sub-Item (1) (i) of this Rule for the previous calendar year. The report shall be submitted on a form prescribed and approved by the Division.
- (2) Steam sterilization requirements:
- (a) Steam under pressure shall be provided to maintain a minimum temperature of 250 degrees Fahrenheit for 45 minutes at 15 pounds per square inch of gauge pressure during each cycle; or other combinations of parameters that are shown to effectively treat the waste.
  - (b) The steam sterilization unit shall be provided with a chart recorder which accurately records time and temperature of each cycle.
  - (c) The steam sterilization unit shall be provided with a gauge which indicates the pressure of each cycle.
  - (d) Monitoring under conditions of full loading for effectiveness of treatment shall be performed no less than once per week through the use of biological indicators or other methods approved by the Division.
  - (e) Regulated medical waste may be disposed of until or unless monitoring as required in ~~Subparagraph~~ Sub-Item (2)(d) of this Rule does not confirm effectiveness.
  - (f) A log of each test of effectiveness of treatment performed shall be maintained and shall include the type of indicator used, date, time, and result of test.
- (3) Incineration requirements:
- (a) Regulated medical waste shall be subjected to a burn temperature in the primary chamber of not less than 1200 degrees Fahrenheit.
  - (b) Automatic auxiliary burners which are capable, excluding the heat content of the wastes, of independently maintaining the secondary chamber temperature at the minimum of 1800 degrees Fahrenheit shall be provided. Interlocks or other process control devices shall be provided to prevent the introduction of waste material to the primary chamber until the secondary chamber achieves operating temperature.
  - (c) Gases generated by the combustion shall be subjected to a minimum temperature of 1800 degrees Fahrenheit for a period of not less than one second.
  - (d) Continuous monitoring and recording of primary and secondary chamber temperatures shall be performed. Monitoring data shall be maintained for a period of three years.
  - (e) An Air Quality Permit shall be obtained from the Division of Environmental Management prior to construction and operation.
  - (f) A plan of procedures for obtaining representative weekly and monthly composite ash samples shall be submitted for Division approval prior to system start-up and operation. If design or operation of the system is substantially changed or modified, or if the waste composition, loading rate or loading method are substantially

changed, the ash sampling plan will be subject to modification to accommodate such changes. Ash sampling procedures shall be initiated at the time the incineration system is first started for normal operation.

- (g) As a minimum, a representative sample of about one kilogram (2.2 lb) shall be collected once for every eight hours of operation of a continuously fed incinerator; once for every 24 hours of operation of an intermittently operated incinerator; or once for every batch of a batch loaded incinerator. The samples shall be collected from either the discharge of the ash conveyor or from the ash collection containers prior to disposal. Samples shall be composited in a closed container weekly and shall be thoroughly mixed and reduced to a representative sample. These shall be composited into monthly samples. For the first three months of operation, each monthly sample shall be analyzed.
- (h) For the remainder of the first year of operation, representative monthly samples shall be composited into a quarterly sample and analyzed at the end of each quarter.
- (i) After the first year, representative samples shall be analyzed at least twice a year.
- (j) Ash samples shall be tested in accordance with provisions of 15A NCAC 13B .0103(e) and submitted to the N.C. Solid Waste Section.
- (k) A log shall be kept documenting ash sampling, which shall include the date and time of each sample collected; the date, time, and identification number of each composite sample; and the results of the analyses, including laboratory identification.
- (l) Records of stack testing as prescribed in the Air Quality Permit shall be maintained at the facility.
- (m) Existing generating facilities shall conduct one weekly representative ash sampling and testing in accordance with ~~Subparagraphs~~ Sub-Items (3)(f), (g) and (j) of this Rule annually during the second quarter of each calendar year.
- (4) Chemical treatment requirements:
  - (a) Cultures of throat, urine, sputum, skin

and genitourinal tract which contain only the following organisms; N. gonorrhea, E. coli, staphylococcus, proteus, Candida albicans, and B. cereus or normal flora in individual plates or tubes containing 5-20 ml media shall be covered, for a minimum of one hour, with a 1:5 dilution of household bleach (5.25 percent sodium hypochlorite) in water. The solution shall remain on the treated plates which are to be stacked in a plastic bag prior to disposal. The bag is to be sealed to prevent leakage.

- (b) Approval for other types of chemical treatment must be obtained from the Division. Request for approval must be substantiated by results of demonstrated effectiveness of the chemical to treat the specific microbiological agent(s) of concern for the waste disposed. Consideration must be given to such factors as temperature, time of contact, pH, concentration and the presence and state of dispersion, penetrability and reactivity of organic material at the site of application.
- (c) A written plan must be maintained at the facility and units of the facility as necessary to ensure consistent procedures are used to treat the waste.

(5) Microwave treatment requirements:

- (a) Microwave energy of appropriate output frequency shall be provided such that a minimum temperature of 95 degrees Centigrade (203 degrees Fahrenheit) is maintained for a minimum of 30 minutes each cycle; or other combinations of parameters that are shown to effectively treat the waste.
- (b) The microwave system shall be provided with a means to continually monitor and record time and temperature of each cycle.
- (c) Monitoring under conditions of full loading for effectiveness of treatment shall be performed through the use of a biological indicator or other methods approved by the Division. Testing shall be performed no less than once per week or as specified by the Division. Additional testing shall be performed if temperature/time monitoring indicates a variation from requirements in Sub-Item (5)(a) of this Rule.

- (d) A log of each test of effectiveness of treatment performed shall be maintained and shall include the type of indicator used, date, time, and result of test.
- (e) Regulated medical waste may be disposed of until or unless monitoring as required in Sub-Item (5)(c) of this Rule does not confirm effectiveness.

Statutory Authority G.S. 130A-309.26.

\* \* \* \* \*

**Notice** is hereby given in accordance with G.S. 150B-21.2 that the EHNHR - Commission for Health Services intends to adopt rule cited as 15A NCAC 18A .1969 and amend rules cited as 15A NCAC 18A .1948, .1956 - .1957.

**The** proposed effective date of this action is April 1, 1993.

**The** public hearing will be conducted at 1:30 p.m. on January 20, 1993 at the Highway Building, First Floor Auditorium, 1 South Wilmington Street, Raleigh, North Carolina.

**Reason for Proposed Actions:**

15A NCAC 18A .1948 - To provide clarifications related to the reclassification of sites for the use of conventional, modified, or alternative ground absorption sewage treatment and disposal systems specified in the rules. This Paragraph is being moved from Rule .1957(c) since it deals with sites not alternative systems.

15A NCAC 18A .1956 - To provide correct rule reference in light of moving Rule .1957(c) to .1948(d). To provide for the approval of experimental or innovative nitrification trenches or lines under the provisions of Rule .1969.

15A NCAC 18A .1957 - To provide correct rule reference in light of moving Rule .1957(c) to .1948(c). To move Paragraph (c) to Rule .1948 for consistency of rule structure and clarity.

15A NCAC 18A .1969 - To meet the requirements of G.S. 130A-343 requiring the establishment of a uniform and systematic procedure for the application, review, permitting, testing, and approval of

experimental and innovative wastewater systems.

**Comment Procedures:** All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629, (919)733-4618. If you desire to speak at the public hearing, notify John P. Barkley at least 3 days prior to the public hearing. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or address proposed changes from staff pursuant to comments made during the public hearing process.

IT IS VERY IMPORTANT THAT ALL INTERESTED AND POTENTIALLY AFFECTED PERSONS, GROUPS, BUSINESSES, ASSOCIATIONS, INSTITUTIONS, OR AGENCIES MAKE THEIR VIEWS AND OPINIONS KNOWN TO THE COMMISSION FOR HEALTH SERVICES THROUGH THE PUBLIC HEARING AND COMMENT PROCESS, WHETHER THEY SUPPORT OR OPPOSE ANY OR ALL PROVISIONS OF THE PROPOSED RULES. THE COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).

## CHAPTER 18 ENVIRONMENTAL HEALTH

### SUBCHAPTER 18A - SANITATION

#### SECTION .1900 - SEWAGE TREATMENT AND DISPOSAL SYSTEMS

##### **.1948 SITE CLASSIFICATION**

(a) Sites classified as SUITABLE may be utilized for a ground absorption sewage treatment and disposal system consistent with these Rules. A suitable classification generally indicates soil and site conditions favorable for the operation of a ground absorption sewage treatment and disposal system or have slight limitations that are readily overcome by proper design and installation.

(b) Sites classified as PROVISIONALLY SUITABLE may be utilized for a ground absorption sewage treatment and disposal system consistent with these Rules but have moderate

limitations. Sites classified Provisionally Suitable require some modifications and careful planning, design, and installation in order for a ground absorption sewage treatment and disposal system to function satisfactorily.

(c) Sites classified UNSUITABLE have severe limitations for the installation and use of a properly functioning ground absorption sewage treatment and disposal system. An improvement permit shall not be issued for a site which is classified as UNSUITABLE. However, where a site is UNSUITABLE, it may be reclassified PROVISIONALLY SUITABLE if a special investigation indicates that a modified or alternative system can be installed in accordance with Rules .1956 or .1957 of this Section.

(d) A site classified as UNSUITABLE may be used for a ground absorption sewage treatment and disposal system specifically identified in Rules .1955, .1956, or .1957 of this Section or a system approved under Rule .1969 if written documentation, including engineering, hydrogeologic, geologic or soil studies, indicates to the local health department that the proposed system can reasonably be expected to function satisfactorily. Such sites shall be reclassified as PROVISIONALLY SUITABLE if the local health department determines that the adequate substantiating data indicate that:

- (1) a ground absorption system can be installed so that the effluent will receive adequate treatment;
- (2) the effluent will not contaminate groundwater or surface water; and
- (3) the effluent will not be exposed on the ground surface or be discharged to surface waters where it could come in contact with people, animals, or vectors.

The State shall review the substantiating data if requested by the local health department.

*Statutory Authority G. S. 130A-335(c).*

## **.1956 MODIFICATIONS TO SEPTIC TANK SYSTEMS**

The following are modifications to septic tank systems which may be utilized to overcome selected soil and site limitations. Except as required in this Rule, the provisions for design and installation of Rule .1955 of this Section shall apply:

- (1) Sites classified UNSUITABLE as to soil depth or soil wetness may be reclassified as PROVISIONALLY SUITABLE with respect to soil depth or soil wetness conditions by utilizing shallow placement of nitrification trenches in the naturally occurring soil. Shallow trenches may be used where at least 24 inches of naturally occurring soil are present above saprolite, rock, or soil wetness conditions and all other factors are PROVISIONALLY SUITABLE or SUITABLE. Shallow trenches shall be designed and constructed to meet the vertical separation requirements in Rule

.1955(m) of this Section. The long-term acceptance rate shall be based on the most hydraulically limiting naturally occurring soil horizon within 24 inches of the ground surface or to a depth of one foot below the trench bottom, whichever is deeper. Soil cover above the original grade shall be placed at a uniform depth over the entire nitrification field and shall extend laterally five feet beyond the nitrification trench. The soil cover shall be placed over a nitrification field only after proper preparation of the original ground surface. The type and placement of soil cover shall be approved by the local health department.

- (2) Sites classified UNSUITABLE as to soil wetness conditions or restrictive horizons may be reclassified PROVISIONALLY SUITABLE as to soil wetness conditions or restrictive horizons when:
  - (a) Soils are Soil Groups I or II with SUITABLE structure, and clay mineralogy;
  - (b) Restrictive horizons, if present, are less than three inches thick or less than 12 inches from the soil surface;
  - (c) Modifications can be made to meet the requirements in Rule .1955(m) of this Section for the separation between the water table and the bottom of the nitrification trench at all times and when provisions are made for maintenance of the drainage systems;
  - (d) Easements are recorded and have adequate width for egress and ingress for maintenance of drainage systems serving two or more lots;
  - (e) Maintenance of the drainage system is made a condition of any permit issued for the use or operation of a sanitary sewage system; and
  - (f) Drainage may be used in other types of soil when the requirements of Rule .1957(e) .1948(d) in this Section are met.
- (3) Modified nitrification trenches or lines, including large diameter pipe (greater than four inches I.D.), and specially designed porous block systems may be permitted by the local health department.
  - (a) Gravelless nitrification trench systems may be substituted for conventional trench systems on any site found to be suitable or provisionally suitable in accordance with Rules .1940 to .1948 of this Section to eliminate the need for gravel, minimize site disturbance, or for other site planning considerations. Gravelless nitrification trench systems shall not be used, however, where wastes contain high amounts of grease and oil, such as restaurants.
  - (i) Large diameter pipe systems shall consist of eight-inch or ten-inch (inside diameter), corrugated, polyethylene tubing encased in a nylon, polyester, or nylon/polyester blend filter wrap installed in a nitrification trench, 12 or more inches wide and backfilled with soil classified as soil group I, II, or III. Nitrification area requirement shall be determined in accordance with Rules .1955(b) and .1955(c), or in Rule .1956(6)(b), Table III of this Section, when applicable, with eight-inch tubing considered equivalent to a two-foot-wide conventional trench and ten-inch tubing considered equivalent to a two and one-half-foot-wide conventional trench. The long-term acceptance rate shall not exceed 0.8 gallons per day per square foot. Tubing and fittings shall comply with the requirements of ASTM F-667, ~~which has been adopted by reference in accordance with G.S. 150B-14(e), which is hereby incorporated by reference including any subsequent amendments and editions.~~ Copies of the standards may be inspected in and copies obtained from the Division of Environmental Health, P.O. Box 27687, Raleigh, NC 27611-7687 at no cost. The corrugated tubing shall have two rows of holes, each hole between three-eighths and one-half-inch in diameter, located 120 degrees apart along the bottom half of the pipe (each 60 degrees from the bottom center line) and staggered so that one hole is present in the valley of each corrugation. The tubing shall be marked with a visible top location indicator, 120 degrees away from each row of holes.  
Filter wrap shall be spun, bonded, or spunlaced nylon, polyester, or nylon/polyester blend nylon filter wrap meeting the following minimum requirements:

Unit Weight:  $\text{Oz/yd}^2 = 1.0$

Sheet Grab Tensile: MD - 23 lbs.

Trapezoid Tear: ~~MC~~ MD - 6.2 lbs.

XD - 5.1 lbs.

Mullen Burst:PSI = 40

KPa = 276

Frazier Air Perm. CFM/ft @ 0.5 "H<sub>2</sub>O: 500"

Corrugated Tubing shall be covered with filter wrap at the factory and each joint shall be immediately encased in a black polyethylene sleeve which shall continue to encase the large diameter pipe and wrap until just prior to installation in the trench. Large diameter pipe systems shall be installed in accordance with this Rule and the manufacturer's guidelines. The trench bottom and pipe shall be level (with a maximum fall of one inch in 100 feet). Filter wrap encasing the tubing shall not be exposed to sunlight (ultraviolet radiation) for extended periods. Rocks and large soil clumps shall be removed from backfill material prior to being used. Clayey soils (soil group IV) shall not be used for backfill. The near end of the large diameter pipe shall have an eight-inch by four-inch offset adaptor (small end opening at top) suitable for receiving the pipe from the septic tank or distribution device and making a mechanical joint in the nitrification trench.

- (ii) A Prefabricated, Permeable Block Panel System (PPBPS), utilizing both horizontal and vertical air chambers and special construction to promote downline and horizontal distribution of effluent, may be used under the following conditions:
  - (A) the soil and site criteria of this Section shall be met;
  - (B) in calculating the required linear footage for a PPBPS's nitrification field, the linear footage for the nitrification line as determined in Rule .1955 (b) and (c), or in Rule .1956 (6)(b), Table III of this Section when applicable, shall be multiplied by 0.5 for a 16 inch PPBPS;
  - (C) installation of the PPBPS shall be in accordance with these Rules except:
    - (I) the PPBPS trench shall be located not less than eight feet on centers;
    - (II) the installation shall be in accordance with the manufacturer's specifications; and
    - (III) the sidewalls of nitrification trenches placed in Group IVa soils shall be raked to open pores which were damaged or sealed during excavation;
  - (D) where design sewage flow is more than 480 gallons per day, the system shall be pressure-dosed; and
  - (E) the long-term acceptance rate shall not exceed 0.8 gallons per day per square foot.
- (b) Other types of nitrification trenches or lines may be approved by the local health department on a site-specific basis ~~provided substantiating data in accordance with Rule .1957(e) .1969 of this Section, are submitted which indicate that the proposed nitrification trench or line will perform equal to or better than a conventional trench or line.~~
- (4) Sites classified as UNSUITABLE as to soil wetness conditions because of the presence of lateral water movement may be reclassified PROVISIONALLY SUITABLE as to soil wetness conditions when such water is intercepted and diverted to prevent saturation of the soil absorption system.
- (5) Stable slopes greater than 30 percent may be reclassified as PROVISIONALLY SUITABLE when:
  - (a) The soil characteristics can be classified as SUITABLE or PROVISIONALLY SUITABLE to a depth of at least one foot below the bottom of the nitrification trench at the upslope side of the trench;
  - (b) Surface water runoff is diverted around the nitrification field if necessary to prevent scouring or erosion of the soil over the field; and
  - (c) The finished grade over the nitrification field site is returned to the original topography and adequately seeded, unless otherwise specified by the local health department.
- (6) Sites classified UNSUITABLE as to soil depth, with saprolite present, may be reclassified PROVISIONALLY SUITABLE as to soil depth when the provisions of this Paragraph are met.
  - (a) An investigation of the site using pits or trenches at locations and to depths specified by the local health department shall be conducted. The following physical properties and characteristics must be present:
    - (i) the saprolite shall be weathered from acidic (granite, gneiss, or schist) parent rock types of



- metamorphic or igneous origin;
- (ii) the saprolite texture shall be suitable and saprolite shall have less than 20 percent clay;
- (iii) clay mineralogy shall be suitable;
- (iv) the saprolite consistence shall be loose, friable to very friable when moist as determined in place and nonsticky or nonplastic when wet;
- (v) the saprolite shall be overlain by at least one foot of **SUITABLE** or **PROVISIONALLY SUITABLE** naturally occurring soil; and
- (vi) the saprolite shall have no continuous joints or fractures relic of parent rock to a depth of two feet below the proposed trench bottom.
- (b) Table III shall be used in determining the long-term acceptance rate for septic tank systems installed pursuant to Paragraph (6) of this Rule. The long-term acceptance rate shall be based on the most hydraulically limiting, naturally occurring saprolite to a depth of two feet below trench bottom.

**TABLE III**

<u>SAPROLITE</u> <u>GROUP</u>	<u>SAPROLITE</u> <u>TEXTURAL CLASSES</u>	<u>LONG-TERM</u> <u>ACCEPTANCE RATE</u>
		<u>gpd/ft<sup>2</sup></u>
I	Sands	Sand 0.6 - 0.5
		Loamy Sand 0.5 - 0.4
II	Coarse Loams (with less Loam than 20% clay)	Sandy Loam 0.4 - 0.3
		0.3 - 0.1

If a low pressure pipe system is used, the long term acceptance rate in Table III shall be reduced by one-half and the system shall be designed in accordance with Rule .1957(a) of this Section, except that Rule .1957 (a)(2)(B) and Rule .1957(a)(3) shall not apply. Saprolite textural classifications shall be determined from disturbed materials and determined by Rule .1941(a)(1) of this Section. The local health department may require low-pressure distribution in conventional nitrification trenches, or other modifications available under this Rule, to insure adequate effluent treatment and disposal.

- (c) Only ground absorption systems with a design daily flow of 480 gallons or less shall be installed on sites reclassified pursuant to this Paragraph [Rule .1956(6)].
- (d) The nitrification field shall be constructed using nitrification trenches with a maximum width of three feet and a maximum depth of two feet on the downslope side of the nitrification trench. The bottom of a nitrification trench shall be a minimum of two feet above rock or saprolite that does not meet the requirements of Subparagraph (6)(a) of this Rule. However, where **SUITABLE** or **PROVISIONALLY SUITABLE** soil underlies the trench bottom, this separation distance may be reduced by subtracting the actual soil depth beneath the trench bottom from 24 inches to establish the minimum separation distance from the trench bottom to rock.
- (e) The bottom of any nitrification trench shall be a minimum of two feet above any wetness condition.
- (f) Surface and subsurface interceptor drains may be required.
- (g) Exceptions to the provisions of Rule .1950(a) found in Rule .1950 and .1951 of this Section shall not apply to systems installed pursuant to this Paragraph [Rule .1956(6)].

*Statutory Authority G.S. 130A-335(e) and (f).*

#### **.1957 DESIGN CRITERIA FOR DESIGN OF ALTERNATIVE SEWAGE SYSTEMS**

(a) **LOW-PRESSURE PIPE SYSTEMS:** Low-pressure pipe (LPP) systems with a two to five-foot pressure head may be utilized on sites which are **SUITABLE** or **PROVISIONALLY SUITABLE** for conventional or modified systems and on sites where soil and site conditions prohibit the installation of a conventional or modified septic tank system if the requirements of this Paragraph are met.

- (1) The LPP system shall consist of the following basic components:

- (A) a network of small-diameter (one to two inches) perforated PVC 160 psi pipe or equivalent placed

in naturally occurring soil at shallow depths (generally 12 to 18 inches) in narrow trenches not less than eight inches in width and spaced not less than five feet on center. Trenches shall include at least five inches of washed stone or washed gravel below the pipe and two inches above the pipe; and four inches of soil cover.

- (B) a properly designed, two-compartment septic tank or other approved pretreatment system, and a pumping or dosing tank;
- (C) a watertight supply manifold pipe, of Schedule 40 PVC or equivalent, for conveying effluent from the dosing chamber to the low-pressure network.
- (2) The soil and site criteria for LPP systems shall meet the following minimum requirements:
  - (A) LPP nitrification fields shall not be installed on slopes in excess of ten percent unless special design procedures to assure proper distribution of effluent over the nitrification field are approved. Landscaping of the LPP distribution field shall be constructed to shed rainwater or runoff. All other requirements of Rule .1940 of this Section shall be met.
  - (B) Site suitability for an LPP system shall be based on the first 24 inches of soil beneath the naturally occurring soil surface. This 24 inches shall consist of SUITABLE or PROVISIONALLY SUITABLE soil as determined in accordance with Rules .1941 through .1944 and .1956 of this Section.
  - (C) Location of the septic tank, other approved pretreatment unit, pumping or dosing chamber, and nitrification field shall be in accordance with Rule .1950 of this Section. Horizontal distances from the nitrification field shall be measured from a margin two and one-half feet beyond the lateral and manifold pipes.
  - (D) There shall be no soil disturbance of the site or repair area for an LPP system except the minimum required for installation.
  - (E) The available space requirements of Rule .1945 of this Section shall apply.
- (3) Table IV shall be used in determining the long-term acceptance rate for LPP systems. The long-term acceptance rate shall be based on the most hydraulically limiting, naturally occurring soil horizon within two feet of the ground surface or to a depth of one foot below the trench bottom, whichever is deeper.

TABLE IV

<u>SOIL GROUP</u>	<u>SOIL TEXTURAL CLASSES</u> <u>(USDA CLASSIFICATION)</u>		<u>LONG-TERM</u> <u>ACCEPTANCE RATE</u>
			<u>gpd/ft<sup>2</sup></u>
I	Sands (With S or PS structure and clay mineralogy)	Sand Loamy Sand	0.6 - 0.4
II	Coarse Loams (With S or PS structure and clay mineralogy)	Sandy Loam Loam	0.4 - 0.3
III	Fine Loams (With S or PS structure and clay mineralogy)	Sandy Clay Loam Silt Loam Clay Loam Silty Clay Loam Silt	0.3 - 0.15

IV	Clays (With S or PS structure and clay mineralogy)	Sandy Clay Silty Clay Clay	0.2 - 0.05
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The long-term acceptance rate shall not exceed the mean rate for the applicable soil group for food service facilities, meat markets, and other places of business where accumulation of grease can cause premature failure of a soil absorption system. Long-term acceptance rates up to the maximum for the applicable soil group may be permitted for facilities where data from comparable facilities indicates that the grease and oil content of the effluent will be less than 30 mg/l and the chemical oxygen demand (COD) will be less than 500 mg/l.

- (4) In calculating the number of square feet for the nitrification field, the design sewage flow shall be divided by the long-term acceptance rate from Table IV. In calculating the minimum length of trenches in the LPP system, the total square footage of the nitrification field shall be divided by five feet.
- (5) Low-pressure systems shall be designed for uniform distribution of effluent. The trenches shall be level and parallel to the ground elevation contours.
  - (A) The maximum lateral length shall yield no more than a ten-percent difference in discharge rate between the first and last hole along the lateral.
  - (B) Minimum hole size shall be 5/32-inch for at least two-thirds of the field lateral lines. Smaller holes (no less than 1/8-inch) may be used in no more than one-third of the lateral lines where necessary to balance flow distribution on sloping sites. However, for systems serving restaurants, foodstands, meat markets and other establishments where effluent is expected to have a high clogging potential, the minimum hole size shall be 5/32-inch.
  - (C) Maximum hole spacing shall be as follows: Soil Group I, five feet; Soil Group II, six feet; Soil Group III, eight feet; and Soil Group IV, ten feet.
  - (D) The following design provisions are required for sloping sites:
    - (i) Separately valved manifolds are required for all subfield segments where the elevation difference between the highest and lowest laterals exceeds three feet.
    - (ii) The hole spacing, hole size or both shall be adjusted to compensate for relative head differences between laterals branching off a common supply manifold and to compensate for the bottom lines receiving more effluent at the beginning and end of a dosing cycle. The lateral network shall be designed to achieve a ten to 30 percent higher steady state (pipe full) flow rate into the upper lines, relative to the lower lines, depending on the amount of elevation difference.
    - (iii) Maximum elevation difference between the highest and lowest laterals in a field shall not exceed ten feet unless the flow is hydraulically split between subfield segments without requiring simultaneous adjustment of multiple valves.
  - (E) Turn-ups shall be provided at the ends of each lateral, constructed of Schedule 40 PVC pipe or equivalent, and protected with sleeves of larger diameter pipe (six inches or greater). Turn-ups and sleeves shall be cut off and capped at or above the ground surface, designed to be protected from damage, and easily accessible.
  - (F) The supply manifold shall be sized large enough relative to the size and number of laterals served so that friction losses and differential entry losses along the manifold do not result in more than a 15 percent variation in discharge rate between the first and last laterals.
    - (i) The ratio of the supply manifold inside cross sectional area to the sum of the inside cross sectional areas of the laterals served shall exceed 0.7:1.
    - (ii) The reduction between the manifold and connecting laterals shall be made directly off the manifold using reducing tees.
    - (iii) cleanouts to the ground surface shall be installed at the ends of the supply manifold.
  - (G) Gate valves shall be provided for pressure adjustment at the fields whenever the supply line exceeds 100 feet in length. Valves shall be readily accessible from the ground surface and adequately protected in valve boxes.
- (6) Septic tanks, pump tanks, pump dosing systems, siphons, and siphon dosing tanks shall be provided

in accordance with Rule .1952 of this Section.

- (A) Design flow rate shall be based upon delivering two feet to five feet of static pressure head at the distal end of all lateral lines.
- (B) Dose volume shall be between five and ten times the liquid capacity of the lateral pipe dosed, plus the liquid capacity of the portions of manifold and supply lines which drain between doses.

(b) **FILL SYSTEM:** A fill system (including new and existing fill) is a system in which all or part of the nitrification trench(es) is installed in fill material. A fill system, including an existing fill site, may be approved where soil and site conditions prohibit the installation of a conventional or modified septic tank system if the requirements of this Paragraph are met.

- (1) Fill systems may be installed on sites where at least the first 18 inches below the naturally occurring soil surface consists of soil that is suitable or provisionally suitable with respect to soil structure and clay mineralogy, and where organic soils, restrictive horizons, saprolite or rock are not encountered. Further, no soil wetness condition shall exist within the first 12 inches below the naturally occurring soil surface and a groundwater lowering system shall not be used to meet this requirement. Fill systems shall not be utilized on designated wetlands unless the proposed use is specifically approved in writing by the designating agency. The following requirements shall also be met:

- (A) Nitrification trenches shall be installed with at least 24 inches separating the trench bottom and any soil horizon unsuitable as to soil structure, clay mineralogy, organic soil, rock or saprolite. However, if a low pressure pipe system is used, the minimum separation distance shall be 18 inches.
- (B) Nitrification trenches shall be installed with at least 18 inches separating the trench bottom and any soil wetness condition. This separation requirement for soil wetness conditions may be met with the use of a groundwater lowering system only in Soil Groups I and II, with suitable structure and clay mineralogy. However, if a low pressure pipe system is used, the minimum separation distance shall be 12 inches.
- (C) Systems shall be installed only on sites with uniform slopes less than 15 percent. Storm water diversions and subsurface interceptor drains or swales may be required upslope of the system.
- (D) The long-term acceptance rate shall be based on the most hydraulically limiting soil horizon within 18 inches of the naturally occurring soil surface or to a depth one foot below the trench bottom, whichever is deeper. The lowest long-term acceptance rate for the applicable soil group shall be used for systems installed pursuant to this Rule. However, the long-term acceptance rate shall not exceed 1.0 gallons per day per square foot for gravity distribution or 0.5 gallons per day per square foot for low-pressure pipe systems installed on sites with at least 18 inches of Group I soils below the naturally occurring soil surface or to a depth of one foot below the trench bottom, whichever is deeper.
- (E) If the fill system uses low-pressure pipe distribution, all the requirements of Paragraph (a) of this Rule, except Paragraph (a)(2)(B), shall apply. Systems with a design daily flow greater than 480 gallons per day shall use low-pressure pipe distribution.
- (F) Fill material shall have such soil texture to be classified as sand or loamy sand (Soil Group I) up to the top of the nitrification trenches. The final six inches of fill used to cover the system shall have a finer texture (such as Group II, III) for the establishment of a vegetative cover. Existing fill material shall have no more than ten percent by volume of fibrous organics, building rubble, or other debris and shall not have discrete layers containing greater than 35 percent of shell fragments.
- (G) Where fill material is added, the fill material and the existing soil shall be mixed to a depth of six inches below the interface. Heavy vegetative cover or organic litter shall be removed before the additional fill material is incorporated.
- (H) The fill system shall be constructed as an elongated berm with the long axis parallel to the ground elevation contours of the slope.
- (I) The side slope of the fill shall not exceed a rise to run ratio of 1:4. However, if the first 18 inches below the naturally occurring soil surface is Group I soil, the side slope of the fill shall not exceed a rise to run ratio of 1:3.
- (J) The outside edge of the nitrification trench shall be located at least five feet horizontally from the top of the side slope.

- (K) The fill system shall be shaped to shed surface water and shall be stabilized with a vegetative cover against erosion.
- (L) The setback requirements shall be measured from the projected toe of the slope. However, if this setback cannot be met, the setback requirements shall be measured from a point five feet from the nearest edge of the nitrification trench if the following conditions are met:
  - (i) Slope of the site shall not exceed two percent;
  - (ii) The first 18 inches of soil beneath the naturally occurring soil surface shall consist of Group I soils;
  - (iii) The lot or tract of land was recorded on or before December 31, 1989; and
  - (iv) A condition is placed upon the Improvement Permit to require connection to a public or community sewage system within 90 days after such system is available for connection and after it is determined that 300 feet or less of sewer line is required for connection.
- (M) The available space requirements of Rule .1945 of this Section shall apply.
- (2) An existing fill site that does not meet the requirements of Paragraph (b)(1) of this Rule may be utilized for a sanitary sewage system if the following requirements are met:
  - (A) Substantiating data are provided by the lot owner (if not readily available to the local health department) indicating that the fill material was placed on the site prior to July 1, 1977.
  - (B) The fill material placed on the site prior to July 1, 1977 shall have such soil texture to be classified as sand or loamy sand (Group I) for a depth of at least 24 inches below the existing ground surface. This fill material shall have no more than ten percent by volume of fibrous organics, building rubble, or other debris. This fill shall not have discreet layers containing greater than 35 percent of shell fragments. However, if at least 24 inches of Group I fill material was in place prior to July 1, 1977, additional fill with soil texture classified as Group I may be added to meet the separation requirements of Paragraph (b)(2)(D) of this Rule.
  - (C) Soil wetness conditions, as determined by Rule .1942(a) in this Section, are 18 inches or greater below the ground surface of the fill placed on the lot prior to July 1, 1977. This requirement shall be met without the use of a groundwater lowering system.
  - (D) Low-pressure pipe distribution shall be used and shall meet all the requirements of Paragraph (a) of this Rule, except (a)(2)(B). The long-term acceptance rate shall not exceed 0.5 gallons per day per square foot. However, for existing fill sites with 48 inches of Group I soils, conventional nitrification trenches utilizing a maximum long-term acceptance rate of 1.0 gallons per day per square foot may be installed in lieu of low-pressure pipe systems. The minimum separation distance between the trench bottom and any soil wetness condition or any soil horizon unsuitable as to soil structure, clay mineralogy, organic soil, rock, or saprolite shall be 24 inches for low pressure pipe systems and 48 inches for conventional systems. This separation requirement may be met by adding additional Group I soil, but shall not be met with the use of a groundwater lowering system. Where fill is to be added, the requirements of Paragraphs (b)(1)(C), (F), (G), (H), (J), (K), of this Rule and the following requirements shall be met:
    - (i) The side slope of the fill shall not exceed a side slope ratio of 1:3, and;
    - (ii) The setback requirements shall be measured from the projected toe of the slope. However, if this setback cannot be met, the setback requirements shall be measured from a point five feet from the nearest edge of the nitrification trench if the following conditions are met:
      - (I) Slope of the site shall not exceed two percent;
      - (II) The lot or tract of land was recorded on or before December 31, 1989; and
      - (III) A condition is placed upon the Improvement Permit to require connection to a public or community sewage system within 90 days after such system is available for connection and after it is determined that 300 feet or less of sewer line is required for connection.
  - (E) The available space requirements of Rule .1945 of this Section shall apply.
  - (F) The design flow shall not exceed 480 gallons per day.
  - (3) Other fill systems may be ~~installed in fill~~ approved by the local health department on a site-specific basis if the requirements of Paragraph (c) of this Rule are met in accordance with Rule .1948(d) of this Section.
    - ~~(e) A site classified as UNSUITABLE which cannot be approved for a system in accordance with Rule .1956, and Paragraphs (a) or (b) of this Rule may be used for a ground absorption sewage treatment and disposal system if written documentation, including engineering, hydrogeologic, geologic, or soil studies,~~

indicates to the local health department that the proposed system can reasonably be expected to function satisfactorily. Such sites shall be reclassified as PROVISIONALLY SUITABLE if the local health department determines that the adequate substantiating data indicates that:

- (1) ~~a ground absorption system can be installed so that the effluent will receive adequate treatment;~~
- (2) ~~the effluent will not contaminate ground water or surface water; and~~
- (3) ~~the effluent will not be exposed on the ground surface or be discharged to surface waters where it could come in contact with people, animals, or vectors.~~

~~The State shall review the substantiating data if requested by the local health department.~~

(d) (c) Individual aerobic sewage treatment units (ATUs) shall be sited, designed, constructed and operated in accordance with this Rule to serve a design unit with a design flow rate of up to 1500 gallons per day, as determined in Rule .1949(a) or .1949(b) of this Section. ATUs shall not be used, however, where wastes contain high amounts of grease and oil, including restaurants and food service facilities. The strength of the influent wastewater shall be similar to domestic sewage with Biological Oxygen Demand (BOD) and suspended solids not to exceed 300 parts per million. ATUs shall comply with the requirements of the National Sanitation Foundation (NSF) Standard 40 for Individual Aerobic Wastewater Treatment Plants and shall be classified as meeting Class I effluent quality. NSF Standard 40 for Individual Aerobic Wastewater Treatment Plants is hereby ~~adopted by reference in accordance with G.S. 150B-14(e).~~ incorporated by reference including any subsequent amendments and editions. Copies of the standards may be inspected in and copies obtained from the Division of Environmental Health, P.O. Box 27687, Raleigh, N.C. 27611-7687 at no cost. ATUs shall bear the NSF mark and the NSF listed model number or shall bear the certification mark and listed model number of a third party certification program accredited by the American National Standards Institute (ANSI), pursuant to ANSI Policy and Procedures for Accreditation of Certification Programs to certify ATUs in accordance with NSF Standard Number 40. The ANSI Policy and Procedures for Accreditation of Certification Programs is hereby ~~adopted incorporated by reference in accordance with G.S. 150B-14(e) by reference including any subsequent amendments and editions. Copies of the standard may be inspected in and copies obtained from the Division of Environmental Health, P.O. Box 27687, Raleigh, N.C. 27611-7687 at no cost.~~ ATUs shall only be permitted where the unit is to be operated and maintained by a certified wastewater treatment facility operator employed by or under contract to the county in which the unit is located, and in accordance with this Rule.

- (1) ATUs shall be constructed and installed in accordance with the plans which have been approved by the Division of Environmental Health and shall comply with all requirements of this Rule. Procedures for plan review and approval shall be in accordance with Rule .1953 of this Section.
- (2) The rated capacity of ATUs listed as complying with NSF Standard 40 shall not be less than the design daily flow as determined by Rule .1949(a) or .1949(b) of this Section.
- (3) The following are minimum standards of design and construction of ATUs:
  - (A) Blockouts in concrete ATU inlet openings shall leave a concrete thickness not less than one inch in the plant wall. Inlet and outlet blockouts shall be made for a minimum of four inch pipe and a maximum of six inch pipe. No blockouts or openings shall be permitted below the liquid level of the ATU.
  - (B) The inlet into the ATU shall be a straight pipe.
  - (C) The invert of the outlet shall be at least two inches lower in elevation than the invert of the inlet.
  - (D) Interior baffle walls in concrete units shall be reinforced by the placing of six-inch by six-inch No. 10 gauge welded reinforcing wire. The reinforcing wire shall be bent to form an angle of 90 degrees on the ends in order to form a leg not less than four inches long. When the wire is placed in the mold, the four inch legs shall lay parallel with the side wall wire and adjacent to it.
  - (E) Access openings shall be provided in the ATU top. Access shall be provided for cleaning or rodding out the inlet pipe, for cleaning or clearing air or gas passage spaces, as an entrance for inserting the suction hose in compartments that are required to be pumped out, to allow for sampling the effluent, and for access to repair or maintain any system components requiring repair and maintenance. All access openings shall have risers sealed to the top of the ATU and extended at least to six inches above finished grade and designed and maintained to prevent surface water inflow. Rule .1950(i) of this Section shall also be met.
  - (F) Concrete ATUs shall be constructed in accordance with Rule .1954(a)(9), (10), (11) and (12) and .1954(b)(4) of this Section.

- (G) Fiberglass reinforced plastic ATUs shall be constructed with materials capable of resisting corrosion from sewage and sewage gases, and the active and passive loads on the unit walls.

- (i) ATUs shall have the following minimum physical properties:

Ultimate tensile strength: 12,000 psi

Flexural strength: 19,000 psi

Flexural modulus of elasticity: 800,000 psi

- (ii) A vacuum test shall be performed on at least one ATU of each model number by an independent testing laboratory, in accordance with ASTM D-4021, Standard Specification for Glass-Fiber Reinforced Polyester Underground Petroleum Storage Tanks, which is hereby ~~adopted incorporated~~ by reference ~~in accordance with G.S. 150B-14(e)~~ including any subsequent amendments and editions. Copies of the standards may be inspected in and copies obtained from the Division of Environmental Health, P.O. Box 27687, Raleigh, N.C. 27611-7687 at no cost. Unit must withstand negative pressure of 2.5 pounds per square inch (69.3 inches of water) without leakage or failure. Test results shall be included with the specifications that are provided to the state for approval.
- (iii) Composition of the finished unit shall be at least 30 percent fiberglass reinforcement by weight. Minimum wall thickness shall be one-fourth inch. However, a wall thickness of not less than three-sixteenth inch may be allowed in small, isolated areas of the ATU.
- (iv) Interior and exterior surfaces shall have no exposed fibers or projections, no blisters larger than one-fourth inch in diameter, and no pores or indentations deeper than one-sixteenth inch. The tank shall be watertight.
- (H) Prefabricated ATUs other than precast reinforced concrete or fiberglass reinforced plastic units shall be approved on an individual basis based on information furnished by the designer which indicates the unit will provide effectiveness equivalent to reinforced concrete or fiberglass reinforced plastic units.
- (I) ATUs shall bear an imprint identifying the manufacturer, serial number assigned to the manufacturer's plans and specifications approved by the Division of Environmental Health, and the liquid or working capacity of the unit. The imprint shall be located to the right of the blockout or opening made for the outlet pipe on the outside of the unit. ATUs shall also be permanently marked with the date of manufacture adjacent to the unit imprint or on the top of the unit directly above the imprint.
- (J) The design, construction, and operation of ATUs shall prevent bypass of wastewater.
- (K) Electrical circuits to the ATU shall be provided with manual circuit disconnects within a watertight, corrosion-resistant, outside enclosure (NEMA 4X or equivalent) adjacent to the ATU securely mounted at least 12 inches above the finished grade. Control panels provided by the manufacturer shall be installed in a watertight, corrosion-resistant enclosure (NEMA 4X or equivalent) adjacent to the unit or on the side of the facility readily visible from the unit and accessible by maintenance personnel. Conductors shall be conveyed to the disconnect enclosure and control panel through waterproof, gasproof, and corrosion-resistant conduits. Splices and wire junctions, if needed, shall be made outside the ATU in a watertight, corrosion-resistant enclosure (NEMA 4X or equivalent) securely mounted adjacent to the unit at least 12 inches above the finished grade. Wire grips, duct seal, or other suitable material shall be used to seal around wire and wire conduit openings inside the ATU and disconnect enclosure. The ATU shall have an alarm device or devices to warn the user or operator of a unit malfunction or a high water condition. The alarm shall be audible and visible by system users and securely mounted adjacent to the ATU, on the side of the facility in clear view of the unit, or inside the finished occupied space of the facility. If mounted outside, the alarm shall meet NEMA 4X standards or equivalent. The alarm circuit or circuits shall be supplied ahead of any ATU electrical control circuit overload and short circuit protective devices.
- (4) A settling tank shall be required prior to an ATU serving a design unit with a design daily flow greater than 500 gallons, as determined in Rule .1949(a) or .1949(b) of this Section. The liquid capacity of the settling tank shall be at least equal to the design daily flow as determined in Rule

- .1949(a) or (b) of this Section. The settling tank may either be an approved prefabricated septic tank or another tank specially designed for a specific individual aerobic sewage treatment plant and approved by the Division of Environmental Health as a part of the plans for the plant.
- (5) Ground absorption systems receiving effluent from approved ATUs may be used on sites classified as suitable or provisionally suitable for conventional, modified, or alternative systems in accordance with this Section. The following modifications to siting and design criteria shall be acceptable:
- (A) The minimum horizontal setback requirements of Rule .1950(a) of this Section shall be met, except as follows:
- |  |                 |
|--|-----------------|
| (i) Any private water supply source, except any uncased well or spring | 50 feet.        |
| (ii) Streams classified as WS-I  | 70 feet.        |
| (iii) Waters classified as SA  | 70 feet.        |
| (iv) Other coastal waters not classified as SA                         | 35 feet.        |
| (v) Any other stream, canal, marsh, or other surface waters            | 35 feet.        |
| (vi) Any Class I or Class II reservoir                                 | 70 feet.        |
|  | from normal     |
|  | pool elevation. |
| (vii) any permanent storm water retention pond.                        | 35 feet.        |
|  | from flood      |
|  | pool elevation. |
| (viii) Any other lake or pond  | 35 feet.        |
|  | from normal     |
|  | pool elevation. |
- (B) The requirements of Rules .1955(m), .1956(1), .1956(2), .1956(6), .1957(b)(1), and .1957(b)(2) of this Section shall be met, except as follows:
- (i) A low-pressure pipe system shall not be required where the separation between the bottom of the nitrification trench and any soil wetness condition is at least 12 inches, but less than 18 inches, and more than six inches of this separation consists of Group I soils.
- (ii) The restriction in Rule .1956(6)(a)(v) of this Section that saprolite be overlain by at least one foot of suitable or provisionally suitable naturally occurring soil shall not apply.
- (iii) For new fill systems, a low pressure pipe system shall not be required in order for the minimum separation distance between the trench bottom and any unsuitable soil horizon, rock, or saprolite to be reduced to 18 inches.
- (iv) For existing fill systems, the minimum separation requirements of Rule .1957(b)(2)(D) of this Section shall be reduced from 48 to 36 inches for conventional systems and from 24 to 18 inches for low-pressure pipe system.
- (C) The maximum long-term acceptance rate shall be increased by 25 percent for any ground absorption system in soils which are Groups I or II with suitable structure and clay mineralogy. No other reductions in linear footage of nitrification trench or system area shall be applied, except where based on an adjusted design daily sewage flow rate granted in accordance with Rule .1949(c) of this Section.
- (6) Prior to issuance of an Operation Permit for an ATU, the manufacturer or his licensed representative shall certify that the unit has been properly installed and a contract for operation and maintenance shall have been executed between the unit owner and the county in accordance with Rule .1961(b) of this Section. It shall be a condition of the Operation Permit that subsequent owners of an ATU execute such a contract. The contract shall include the specific requirements for maintenance and operation, responsibilities for maintenance and operation, responsibilities of the owner and system operator, provisions that the contract shall be in effect for as long as the system is in use, and other requirements for the continued proper performance of the ATU. A condition of the Operation Permit shall be that the unit continue to perform in accordance with Class I effluent quality requirements of the National Sanitation Foundation (NSF) Standard Number 40 effective on the date the improvement permit was issued.
- (7) Performance monitoring shall be carried out by the operator.
- (A) During each inspection, the operator shall confirm proper mechanical performance, conduct a visual check for unusual color, clogging, oily film, odors, foam, measure settleable aeration



chamber solids, and ascertain the need for removing solids, backwash and cleaning of filters, and other maintenance activities. The ground absorption system shall also be inspected and an evaluation of performance shall be made. The operator shall take the necessary steps to assure that needed maintenance is carried out.

- (B) Semi-annually, samples shall be collected by the system operator and analyzed by a state-approved wastewater testing laboratory of the effluent for Five-Day Biological Oxygen Demand, Suspended Solids, and pH. The aeration tank shall be sampled for mixed liquor suspended solids.
- (C) Performance monitoring results shall be reported to the local health department and the state quarterly.
- (D) Remedial action and additional sampling shall be required if monitoring results or inspection indicate that Class I effluent standards are not met.

*Statutory Authority G.S. 130A-335(e) and (f); 130A-342.*

**.1969 EXPERIMENTAL AND INNOVATIVE SYSTEMS, COMPONENTS, OR DEVICES**

Experimental and innovative (E & I) systems are any wastewater systems, system components, or devices that are not specifically described in Rules .1955, .1956, .1957, or .1958 of this Section, including any system for which reductions are proposed in the minimum horizontal or vertical separation requirements or increases are proposed to the maximum long-term acceptance rates of this Section. This Rule shall provide for the approval and permitting of E & I systems.

- (1) An application shall be submitted in writing to the State for an E & I system. The application shall include the following, as applicable:
  - (a) description of the system and its proposed use, including materials used in construction;
  - (b) review of pertinent literature, published research, and previous experience and performance with the system;
  - (c) results of any available testing, research or monitoring of pilot systems or full-scale operational systems conducted by a third party research or testing organization;
  - (d) identity and qualifications of any proposed research or testing organization and the principal investigators, and an affidavit certifying that the organization and principal investigators have no conflict of interest and do not stand to gain financially from the sale of the E & I system;
  - (e) objectives, methodology, and duration of any proposed research or testing;
  - (f) operation and maintenance procedures, system classification, proposed

management entity and system operator; procedure to address system malfunction and replacement or premature termination of any proposed research or testing; and

(h) notification of any proprietary information, system, component, or device.

(2) The State shall review all applications submitted for review. The State shall evaluate at least the following:

(a) the completeness of the application, and whether additional information is needed to continue the review;

(b) whether the system, component or device meets the standards of an innovative system under Paragraph (3) of this Rule, and proposed conditions for use, maintenance and monitoring.

(c) For systems, components, or devices which cannot be approved as an innovative system, whether approval shall be granted for use as an experimental system under Paragraph (4) of this Rule, and proposed conditions for use, research and maintenance.

(3) INNOVATIVE SYSTEMS: In order for a system, component, or device to be approved as an innovative system, the following standards shall be met:

(a) The system, component, or device shall have been demonstrated to perform equal or superior to a system, component or device which is described in Rules .1955, .1956, .1957 or .1958, based upon controlled pilot-scale research studies or statistically-valid monitoring of full-scale operational systems.

(b) Materials used in construction shall be

- equal or superior in physical properties and chemical durability, compared to materials used for similar purposes in systems, components or devices specifically described in Rules .1955, .1956, .1957 or .1958. When a system, component, or device is approved as innovative by the State, the applicant shall be notified in writing. Such notice shall include any conditions for use, monitoring, and operation. A local health department shall issue an Improvement Permit for any innovative system approved by the State upon a finding that the provisions of this Rule including any conditions are met. Use of an innovative system and any conditions shall be described on the Improvement Permit and the Certificate of Completion or Operation Permit.
- (4) EXPERIMENTAL SYSTEMS: A system, component, or device which is not approved as an innovative system may be approved for use as an experimental system as part of a research or testing program which has been approved by the State. The research or testing program shall be conducted by a third party research or testing organization which has knowledge and experience relevant to the proposed research or testing and has no conflict of interest and does not stand to gain financially from the sale of the proposed system.
- (a) To be approved by the State, the proposed research or testing program shall include the following:
- (i) Objectives which address issues which do not enable the system to be approved as an innovative system.
  - (ii) Research design and testing methodology which has a reasonable likelihood of meeting the objectives.
  - (iii) Specification of the number of systems proposed to be installed, the criteria for site selection, system monitoring and reporting procedures, and operation and maintenance requirements.
- The State shall notify the applicant and the applicable local health departments when the proposed research or testing program has been approved for an experimental system.
- (b) A local health department may issue an Improvement Permit for an experimental system when the following conditions are met:
- (i) There is an application for an Improvement Permit in accordance with Rule .1937(c) of this Section, with the proposed use of an experimental system specified.
  - (ii) The proposed site is included as part of an approved research or testing program and any conditions specified for use of the system have been met.
  - (iii) When an experimental system is proposed to serve a residence, place of business or place of public assembly, the provisions for a repair area and backup system of Rule .1945(b) of this Section shall apply, except:
    - (A) When an existing and properly functioning wastewater system is available for immediate use, including connection to a public or community wastewater system; or
    - (B) When the experimental system is used as a repair to an existing malfunctioning system; or
    - (C) When the experimental system is to serve a vehicular, portable structure built on a chassis and designed to be used as a residence, place of business, or place of public assembly without a permanent foundation, in which case sufficient available space shall be reserved for the installation of a replacement system at least equal to the initial experimental system.
  - (iv) When an experimental system is proposed which shall not serve a residence, place of business, or place of public assembly, a repair area or backup system shall not be required.
  - (v) The application for an experimental system shall include statements that the property owner and proposed user(s) of the system are aware of its experimental nature, hold the local health department and State harmless regarding the installation, use, monitoring and performance of the system and are aware that use of the system

may need to be discontinued if the system malfunctions and is found to be non-repairable, or if the proposed research or testing program is prematurely terminated. Such statements shall be signed by the owner and proposed system user(s).

- (vi) The owner of the site on which an experimental system is proposed shall execute a easement granting rights of access to the system at reasonable hours for monitoring and evaluation to the research or testing organization. This easement shall remain valid as long as the system is to be part of the proposed research or testing program. The easement shall be recorded with the county register of deeds.
- (vii) Provisions shall be made for operation and maintenance of the system.
- (c) Any special conditions required for the installation of the experimental system shall be specified in the Improvement Permit. Use of an experimental system and any conditions shall be described on the Improvement Permit and any subsequent operation permits, with provisions for a repair area and backup system specified. A condition of the Improvement Permit shall be that the installation be under the direct field supervision of the research or testing organization.
- (d) All proposed permits for experimental systems shall be reviewed by the State and found to be consistent with the approved research or testing program prior to issuance by the local health department.
- (e) Upon completion of the installation and prior to use, an Experimental System Operation Permit (ESOP) shall be issued by the local health department. The ESOP shall be valid for a specified period of time not to exceed five years. Special maintenance, monitoring and testing requirements shall be specified as permit conditions, in accordance with the approved research or testing program. Failure to carry out these conditions shall be grounds for permit suspension or revocation.
- (f) Prior to expiration of the ESOP and based upon satisfactory system perfor-

mance as determined during the research or testing program, the local health department shall issue an Operation Permit. Premature termination of the research or testing program shall be grounds for ESOP suspension or revocation.

- (g) Upon completion of monitoring, research and testing, the research or testing organization shall prepare a final report including recommendations on future use of the system. The State may recommend incorporation of the system into the rules as a conventional, modified or alternative system; or use as an innovative system in accordance with Paragraph (3) of this Rule; or further research or testing.
- (5) The State shall suspend or revoke the approval of an E & I system or modify the conditions specified for system use upon a finding that the information submitted in the application is changed or falsified, subsequent experience with the system results in altered conclusions about system performance or design, or when superseded by future rules.

*Statutory Authority G. S. 130A-335(e) and (f); 130A-343.*

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*Notice* is hereby given in accordance with G.S. 150B-21.2 that the EHNR-Commission for Health Services intends to amend rules cited as 15A NCAC 19B .0313, .0320 - .0321, .0503.

*The proposed effective date of this action is April 1, 1993.*

*The public hearing will be conducted at 1:30 p.m. on January 20, 1993 at the Highway Building, First Floor Auditorium, 1 South Wilmington Street, Raleigh, North Carolina.*

***Reason for Proposed Action:***

*15A NCAC 19B .0313 - To specify requirements of evaluating breath-test instruments and improve the efficiency of the statewide alcohol testing program.*

*15A NCAC 19B .0320 and .0321 - To improve the efficiency of Intoxilyzer 5000 operational and maintenance procedures.*

*15A NCAC 19B .0503 - To add three additional alcohol screening test devices to the approved list.*

***Comment Procedures:*** All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629, (919)733-4618. If you desire to speak at the public hearing, notify John P. Barkley at least 3 days prior to the public hearing. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or address proposed changes from staff pursuant to comments made during the public hearing process.

IT IS VERY IMPORTANT THAT ALL INTERESTED AND POTENTIALLY AFFECTED PERSONS, GROUPS, BUSINESSES, ASSOCIATIONS, INSTITUTIONS, OR AGENCIES

MAKE THEIR VIEWS AND OPINIONS KNOWN TO THE COMMISSION FOR HEALTH SERVICES THROUGH THE PUBLIC HEARING AND COMMENT PROCESS, WHETHER THEY SUPPORT OR OPPOSE ANY OR ALL PROVISIONS OF THE PROPOSED RULES. THE COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).

**CHAPTER 19 - HEALTH: EPIDEMIOLOGY**

**SUBCHAPTER 19B - INJURY CONTROL**

**SECTION .0300 - BREATH ALCOHOL TEST REGULATIONS**

**.0313 BREATH-TESTING INSTRUMENTS: REPORTING OF SEQUENTIAL TESTS**

(a) The standards for the approval of breath-testing instruments are as follows:

(1) The commission approves the method of performing chemical analyses through the use of breath-testing instruments of a design and of a model specifically approved by the commission as meeting, to its satisfaction, standards of accuracy, reliability, convenience and efficiency of operation.

(2) The Injury Control Section shall evaluate and recommend to the Commission only those breath-testing instruments which meet the minimum requirements as set forth in the current state purchase and contract bid specifications for automated evidential breath alcohol testing instruments. Such evaluations shall be conducted only when deemed necessary or appropriate by the Director or his representative to improve the efficiency of the statewide alcohol testing program.

(3) The succeeding rules of this Section establish operational and preventive maintenance procedures for breath-testing instruments approved by the commission.

(b) The standards for the reporting of sequential tests are as follows:

(1) In recording the results of a chemical analysis under G.S. 20-139.1(e) and in reporting results for use in court or in an administrative proceeding, the chemical analyst shall report the results of all

tests of breath performed in conducting the chemical analysis. These results may be used for all relevant purposes, but these results may not be used to prove a person's particular alcohol concentration unless a pair of consecutively administered tests do not differ from each other by an alcohol concentration of greater than 0.02.

- (2) In proceedings in court and before administrative agencies, the state may use all breath-test procedures and results for all relevant purposes, but when there is a difference in readings, the state may use only the lower of the two consecutive readings that meet the requirements of Paragraph (b) to prove a person's particular alcohol concentration. "Particular alcohol concentration" is an alcohol concentration that has legal significance under G.S. 20-138.1(a)(2), 20-16.5(b)(4), 20-179(d)(1), and 20-179(m).

*Statutory Authority G.S. 20-16.5(j); 20-139.1(b).*

#### **.0320 INTOXILYZER: MODEL 5000**

The operational procedures to be followed in using the Intoxilyzer, Model 5000 are:

- ~~(1) Insure observation period requirements have been met;~~
- (1) Insure instrument displays time and date;
- ~~(2) Insure instrument displays proper time and date;~~
- (2) Insure observation period requirements have been met;
- (3) Press "START TEST"; when "INSERT CARD" appears, insert test record;
- (4) Enter appropriate information;
- ~~(5) Insure instrument displays expected results from the alcoholic breath simulator;~~  
Verify instrument calibration;
- (6) When "PLEASE BLOW" appears, collect breath sample;
- (7) When "PLEASE BLOW" appears, collect breath sample;
- ~~(8) When test record ejects, remove, and record times and results~~

If the alcohol concentrations differ by more than 0.02, a third or subsequent test shall be administered as soon as feasible by repeating steps (1) through (6), (7) if necessary, and (8), as applicable.

*Statutory Authority G.S. 20-139.1(b).*

#### **.0321 PREVENTIVE MAINTENANCE: INTOXILYZER: MODEL 5000**

The preventive maintenance procedures for the Intoxilyzer Model 5000 to be followed at least once every four months are:

- (1) Verify alcoholic breath simulator thermometer shows 34 degrees, plus or minus .2 degree centigrade;
- (2) Verify instrument displays proper time and date;
- (3) Press "START TEST"; when "INSERT CARD" appears, insert test record;
- (4) Enter appropriate information;
- ~~(5) Verify instrument displays expected results from the alcoholic breath simulator calibration;~~
- (6) When "PLEASE BLOW" appears, collect breath sample;
- (7) When "PLEASE BLOW" appears, collect breath sample;
- ~~(8) When test record ejects, remove and record times and results;~~
- (9) Verify Diagnostic Program;
- (10) Verify alcoholic breath simulator solution is being changed every four months or after 125 tests, whichever occurs first.

A signed original of the preventive maintenance checklist shall be kept on file for at least three years.

*Statutory Authority G.S. 20-139.1(b)(b4).*

### **SECTION .0500 - ALCOHOL SCREENING TEST DEVICES**

#### **.0503 APPROVED ALCOHOL SCREENING TEST DEVICES: CALIBRATION**

(a) The following breath alcohol screening test devices are approved as to type and make:

- (1) ALCO-SENSOR (with two-digit display), made by Intoximeters, Inc.
- (2) ALCO-SENSOR III (with three-digit display), made by Intoximeters, Inc.
- (3) BREATH-ALCOHOL TESTER MODEL BT-3, made by RepCo., Ltd.
- (4) ALCOTEC BREATH-TESTER, made by RepCo., Ltd.
- (5) ALCO-SENSOR IV, manufactured by Intoximeters, Inc.
- (6) PBA 3000, manufactured by Life Loc, Inc.
- (7) SD-2, manufactured by CMI, Inc.

(b) Calibration of alcohol screening test devices shall be verified at least once during each 30 day period of use by employment of a control sample

from an alcoholic breath simulator, or an ethanol/gas standard. The device shall be deemed properly calibrated when the result of 0.09 or 0.10 is obtained.

- (1) Alcoholic breath simulators used exclusively for calibration of alcohol screening test devices shall have the solution changed every 30 days or after 25 calibration tests, whichever occurs first.
- (2) Requirements of Paragraph (b) and Subparagraph (b)(1) of this Rule shall be recorded on an alcoholic breath simulator log designed by the Injury Control Section and maintained by the user agency.

Statutory Authority G.S. 20-16.3.

\* \* \* \* \*

*Notice* is hereby given in accordance with G.S. 150B-21.2 that the EHNR - Commission for Health Services intends to amend rules cited as 15A NCAC 20D .0233 - .0235, .0243, .0248.

*The proposed effective date of this action is April 1, 1993.*

*The public hearing will be conducted at 1:30 p.m. on January 20, 1993 at the Highway Building, First Floor Auditorium, 1 South Wilmington Street, Raleigh, North Carolina.*

*Reason for Proposed Action:* To correct and clarify the current regulations.

*Comment Procedures:* All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629, (919)733-4618. If you desire to speak at the public hearing, notify John P. Barkley at least 3 days prior to the public hearing. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or address proposed

*changes from staff pursuant to comments made during the public hearing process.*

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## CHAPTER 20 LABORATORY SERVICES

### SUBCHAPTER 20D - CERTIFICATION AND IMPROVEMENT

#### SECTION .0200 - LABORATORY CERTIFICATION

##### .0233 CERTIFICATION, CERTIFICATION RENEWAL AND FEES

(a) The Department of Environment, Health, and Natural Resources shall grant certification for the test categories requested upon finding that a laboratory meets the minimum requirements set forth in this Section.

(b) A laboratory may renew its certification every year by payment of the certification fee by December 1 of the preceding year. ~~If the fee has not been paid by December 31 of each year, the laboratory's certification shall not be renewed for the next year, and the laboratory shall apply for recertification pursuant to Rule .0235 of this Section. In addition to payment of the certification fee, an on-site evaluation by a laboratory certification evaluator and compliance with the minimum requirements of this Section are required for renewal. A laboratory which renews its certification shall continue to meet the minimum requirements of this Section in accordance with 15A NCAC 20D .0234.~~

(c) The certificate and information pertaining to certification shall remain the property of the Department of Environment, Health, and Natural Resources and shall be surrendered upon decertification pursuant to Rule .0234 of this Section. All certification information shall be available for public access pursuant to Chapter 132 of North Carolina General Statutes.

(d) The certification fee shall be twenty dollars

(\$20.00) per analyte. The minimum and maximum fee per analyte group shall be as set out in G.S. 130A-326(7). The analyte groups are as follows:

- (1) inorganic chemistry;
- (2) organic chemistry I (synthetic organic chemicals);
- (3) organic chemistry II (volatile organic chemicals);
- (4) total and fecal coliforms; and
- (5) radiochemistry.

The certification fee shall not be prorated nor refunded. Twenty percent shall be due at the time of the application.

*Statutory Authority G.S. 130A-315; 130A-326.*

#### **.0234 CRITERIA AND PROCEDURES: DECERTIFICATION/DENIAL/ DOWNGRADING**

(a) The Department of Environment, Health, and Natural Resources or its delegate may downgrade or deny laboratory certification if the laboratory:

- (1) Demonstrates incompetence or made consistent errors in analyses;
- ~~(2) Failed to correctly analyze performance evaluation samples, including United States Environmental Protection Agency water study, double blind, blind, and on-site samples, or failed to report the results within the specified time;~~
- ~~(3)~~ (2) Failed to report analytical results of performance evaluation samples or compliance samples or maintain records as required by this Section and the Rules Governing Public Water Supplies in 15A NCAC 18C .1500;
- ~~(4)~~ (3) Failed to maintain facilities and equipment in accordance with the minimum requirements of this Section;
- ~~(5)~~ (4) Failed to notify the certification evaluator of major changes such as personnel, equipment, or laboratory location; or
- ~~(6)~~ (5) Violated or aided and abetted in the violation of any provisions of the rules of this Section;

(b) A downgraded laboratory with provisional certification may continue to perform analyses. The provisional status shall continue for at least six months. At the end of six months the laboratory certification shall be reinstated if the laboratory has made corrections and is in compliance with the minimum requirements for certification. If no corrections have been made the laboratory certification may be revoked.

(c) The Department of Environment, Health, and Natural Resources or its delegate may decertify or deny laboratory certification when a laboratory or its employees have done any of the following:

- (1) Knowingly made false statements on any documents associated with certification;
- (2) Falsified results of analyses;
- (3) Submitted performance evaluation samples used for certification determination to another laboratory for analysis;
- (4) Failed to employ approved laboratory methodology in the performance of the analyses required by 15A NCAC 18C .1500;
- (5) Repeatedly failed to correctly analyze performance evaluation samples including United States EPA water study, double blind, blind, and on-site samples or report the results within the specified time in accordance with the requirements of 15A NCAC 20D .0243 and .0251;
- (6) Repeatedly failed to report analytical results of performance evaluation samples or compliance samples or maintain records as required by this Section and the Rules Governing Public Water Supplies in 15A NCAC 18C;
- (7) Failed to satisfy the certification evaluator that the laboratory has corrected deviations identified during the on-site visit within 30 days; or
- (8) Violated or aided and abetted in the violation of any provisions of the rules of this Section.

(d) The Department of Environment, Health, and Natural Resources or its delegate shall notify a laboratory of its intent to decertify, downgrade to provisional status or deny certification. The notice shall be in writing and include reasons for the decision and shall be delivered by certified mail.

(e) This Rule shall not preclude informal conferences concerning a decision to decertify, downgrade to provisional status or deny certification.

*Statutory Authority G.S. 130A-315.*

#### **.0235 RECERTIFICATION**

(a) A laboratory is eligible for recertification six months after decertification, except in the

following instances:

- (1) A laboratory which lost certification for false statements on documents, falsified analytical results, or submitted official performance samples to another laboratory, is eligible for recertification one year after decertification. Application for recertification shall be made in the same way as application for certification as contained in Rule .0233 of this Section;
- (2) A laboratory which lost certification for failure to correctly analyze performance evaluation samples is eligible for recertification 30 days after decertification and after satisfying Rule .0243(b)(4) or .0251(4)(3), or both of this Section.

(b) A laboratory for which certification was not renewed for failure to pay the certification fee by the date required in Rule .0233 of this Section is eligible for recertification 60 days after paying the overdue fee.

*Statutory Authority G.S. 130A-315; 130A-326.*

#### **.0243 CHEMISTRY QUALITY ASSURANCE**

(a) The following general requirements for chemistry quality assurance (QA) shall be met:

- (1) All quality control information shall be available for inspection by the certification officer;
- (2) A manual of analytical methods and the laboratory's QA plan shall be available to the analysts;
- (3) Class S weights or higher quality weights shall be available to make periodic checks on the accuracy of the balances. Checks shall be within range of the manufacturer's guidelines. A record of these checks shall be available for inspection. The specific checks and their frequency are to be as prescribed in the laboratory's QA plan or the laboratory's operations manual. These checks shall be performed at least once a month.
- (4) Color standards or their equivalent, such as built-in internal standards, shall be available to verify wavelength settings on spectrophotometers. These checks shall be within the manufacturer's tolerance limits. A record of the checks shall be available for inspection. The specific checks and

their frequency shall be as prescribed in the laboratory's QA plan or the laboratory's operations manual. These checks shall be performed at least every six months.

(b) The laboratory shall analyze performance samples as follows:

- (1) United States Environmental Protection Agency performance evaluation samples shall be analyzed semi-annually. Results shall be within control limits established by EPA for each analyte for which the laboratory is or wishes to be certified.
- (2) Double blind and blind samples shall be analyzed when submitted to a certified laboratory and results shall be within established control limits; these data shall be of equal weight to the EPA performance evaluation sample data and on site quality control sample data in determining the laboratory's certification status.
- (3) On-site quality control samples shall be analyzed when presented to the laboratory by the certification evaluator and results shall be within established control limits. These data shall be of equal weight to the EPA performance evaluation sample data and the double blind sample data in determining the laboratory's certification status.
- (4) A performance level of 75 percent shall be maintained for each analyte for which a laboratory is or wishes to be certified. This 75 percent average shall be calculated from the ten most recent performance sample data points from the EPA water studies, double-blind, blind, and on-site samples. In the event the laboratory does not have ten data points, the 75 percent average will be calculated on the existing data points, with a minimum of four data points needed before a determination is made.
- (5) Unacceptable performance on any of the samples in Paragraph (b) of this Rule shall be corrected and explained in writing within 30 days and submitted to the certification evaluator.

(c) The minimum daily quality control (QC) for chemistry shall be as follows:

- (1) Inorganic Contaminants:
  - (A) At the beginning of each day that samples are to be analyzed, a standard



curve composed of at least a reagent blank and three standards covering the sample concentration range shall be prepared.

- (B) The laboratory shall analyze a QC sample (EPA QC sample or equivalent) at the beginning of the sample run, at the end of the sample run, and every 20 samples, with recoveries not to exceed  $\pm 10$  percent of the true concentration. The source of this QC sample shall be different from the source used for the calibration standards in ~~Paragraph~~ Subparagraph (c)(1)(A) of this Rule.
- (C) The laboratory shall run an additional standard or QC check at the laboratory's lowest detectable limit for the particular analyte. The laboratory shall not report a value lower than the lowest standard or QC check analyzed.
- (D) The laboratory shall add a known spike to a minimum of 10 percent of the routine samples (except when the method specifies a different percentage, i.e. furnace methods) to determine if the entire analytical system is in control. The spike concentration shall not be substantially less than the background concentration of the sample selected for spiking. The spike recoveries shall not exceed  $\pm 10$  percent of the true value.
- (E) All compliance samples analyzed by graphite furnace shall be spiked to determine absence of matrix interferences with recoveries  $\pm 10$  percent of the true value of the spike concentration.
- (F) The laboratory shall run a duplicate sample every 10 samples with duplicate values within  $\pm 10$  percent of each other.
- (G) Precision and accuracy data may be computed from the analyses of check samples of known value used routinely in each analytical procedure. This data shall be available for inspection by the laboratory evaluator.
- (2) Organic Contaminants:
  - (A) Quality control specified in the approved methods referenced in Rule .0241 of this Section shall be followed.
  - (B) Analysis for regulated volatile organic

chemicals under 15A NCAC 18C .1515 shall only be conducted by laboratories that have received conditional approval by EPA or the Department according to 40 C.F.R. 141.24(g)(10) and (11) which is hereby incorporated by reference including any subsequent amendments and editions. A copy is available for inspection at the Department of Environment, Health, and Natural Resources, Division of Laboratory Services, 306 North Wilmington Street, Raleigh, North Carolina. Copies of 40 CFR 141-143 may be obtained by contacting the EPA Drinking Water Hotline at 800-426-4791 at no charge.

- (C) Analysis for unregulated volatile organic chemicals under 15A NCAC 18C .1516 shall only be conducted by laboratories approved under Subparagraph (c)(2)(B) of this Rule. In addition to the requirements of Subparagraph (c)(2)(B) of this Rule, each laboratory analyzing for EDB and DBCP shall achieve a method detection limit for EDB and DBCP of 0.00002 mg/l, according to the procedures in Appendix B of 40 C.F.R. Part 136 which is hereby incorporated by reference including any subsequent amendments and editions. A copy may be obtained at no charge by contacting the Department of Environment, Health, and Natural Resources, Division of Laboratory Services, 306 North Wilmington Street, Raleigh, North Carolina.

*Statutory Authority G.S. 130A-315.*

#### **.0248 MICROBIOLOGY GENERAL LABORATORY PRACTICES**

(a) The general laboratory practices for microbiological analyses shall be in accordance with those listed in the EPA "Manual for the Certification of Laboratories Analyzing Drinking Water", Chapter 5, Section 4, General Laboratory Practices, which is hereby incorporated by reference including any subsequent amendments and editions, except that Sections ~~4.6.1~~ 4.7.1 through 4.9 are not incorporated by reference. A copy is available for inspection at the Department of Environment,

Health, and Natural Resources, Division of Laboratory Services, 306 North Wilmington Street, Raleigh, North Carolina. Nonprofit organizations or government agencies may obtain a copy by contacting the EPA Drinking Water Hotline at 800-426-4791. Other organizations may obtain a copy from the National Technical Information Service at 800-336-4700 for \$35.00.

(b) In addition, the following laboratory practices shall be followed:

- (1) Media - General Requirements.  
Check each lot of medium with positive and negative culture controls.
- (2) Membrane Filter Media:
  - (A) Use m-Endo broth or agar or LES Endo broth or agar in the single step or enrichment techniques. Ensure that ethanol used in rehydration procedure is not denatured. Prepare medium in a sterile flask and use a boiling water bath or, if constantly attended, a hot plate with a stir bar to bring medium to the boiling point. Do not boil medium. Final pH shall be  $7.2 \pm 0.2$ .
  - (B) Refrigerate MF broth no longer than 96 hours, poured MF agar plates no longer than two weeks, and ampouled m-Endo broth in accordance with manufacturer's expiration date.
- (3) Multiple Tube Fermentation (MTF) Media:
  - (A) Use double strength lauryl sulfate broth or lactose broth in the presumptive test and single strength brilliant green lactose bile (BGLB) broth in the confirmed test. Autoclave media at  $121^{\circ}\text{C}$  for 12 minutes. Final pH shall be  $6.8 \pm 0.2$  or  $7.2 \pm 0.2$  for BGLB broth.
  - (B) If MTF media are refrigerated after sterilization, incubate overnight at  $35^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$  before use. Discard tubes showing growth or bubbles. Use MTF media prepared in tubes with loose fitting closures within one week. Store broth media in screw cap tubes or bottles no longer than three months, provided media are stored in the dark. Discard media if evaporation exceeds 10 percent of original volume.
  - (C) LES Endo agar shall be used for the completed test. Refrigerate medium and use within two weeks.

- (4) Clark's Total Coliform Medium:
  - (A) Autoclave for 12 minutes at  $121^{\circ}\text{C}$ . Allow space between bottles.
  - (B) Final pH shall be  $6.8 \pm 0.2$ .
  - (C) Store prepared medium in screw capped culture bottle no longer than three months; discard if evaporation exceeds 10 percent of original volume.
- (5) EC Medium (for fecal coliforms):
  - (A) Autoclave for 12 minutes at  $121^{\circ}\text{C}$ .
  - (B) Examine tubes after sterilization to insure that inverted inner tubes are free of air bubbles and that the vials are at least partially covered with medium.
  - (C) Incubate refrigerated sterilized medium overnight at  $35^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ ; discard tubes that show growth or bubbles.
  - (D) Store prepared medium in screw cap tubes.
  - (E) Final pH shall be  $6.9 \pm 0.2$ .
- (6) EC + MUG Medium (for detection of fecal coliforms-E. coli)
  - (A) Autoclave medium at  $121^{\circ}\text{C}$  (gas tubes shall not be used)
  - (B) Final pH shall be  $6.9 \pm 0.2$
  - (C) Store prepared medium in screw cap tubes no longer than three months.
- (7) MMO-MUG Test Medium (for Total Coliform and *E. coli*):
  - (A) The laboratory shall not prepare this medium from basic ingredients.
  - (B) Each lot purchased shall be tested for performance by inoculation with three control bacteria: *Escherichia coli*, a total coliform other than *E. coli* (e.g., *Klebsiella pneumoniae*) and a non-coliform (e.g., *Pseudomonas aeruginosa*). These control organisms can be stock cultures or commercially available discs impregnated with the organism. Incubate these controls at  $35^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$  for 24 hours, and read and record result.
  - (C) Do not autoclave.
- (8) Fecal Coliform Membrane Filter Medium  
(for enumeration of fecal coliform in source water):
  - (A) Rehydrate medium in reagent water containing 10 ml of 1 percent rosolic acid in 2N NaOH. Bring it to the

- boiling point; do not autoclave.
- (B) Autoclave for 12 minutes at 121°C.
- (C) Final pH shall be  $7.4 \pm 0.2$ .
- (D) Refrigerate unused prepared medium; discard after 96 hours.
- (9) Heterotrophic Plate Count (HPC) Medium:
  - (A) Autoclave HPC agar at 121°C for 15 minutes.
  - (B) Final pH shall be  $7.0 \pm 0.2$ .
  - (C) Temper melted agar at 44°-46°C before pouring.
  - (D) Hold melted agar no longer than four hours. Do not melt sterile agar medium more than once.

Statutory Authority G.S. 130A-315.

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**Notice** is hereby given in accordance with G.S. 150B-21.2 that the EHNR-Commission for Health Services intends to amend rules cited as 15A NCAC 24A .0101, .0502 - .0503.

**The** proposed effective date of this action is April 1, 1993.

**The** public hearing will be conducted at 1:30 p.m. on January 20, 1993 at the Highway Building, First Floor Auditorium, 1 South Wilmington Street, Raleigh, North Carolina.

**Reason for Proposed Actions:**

15A NCAC 24A .0101 - To establish an annual fee for persons who have registered notice of rule making. This fee will cover copying and mailing costs pursuant to 150B-21.2(b).

15A NCAC 24A .0502 - The current rule for terminating financial eligibility gives the applicant 15 days to show why financial eligibility should not be terminated after we have notified him that we believe financial eligibility was established based on incorrect information on the application form. After that, another 15 day period is allowed for the applicant to appeal the decision. We are advised that this rule is in conflict with G.S. 130A-23 which requires a 60 day period for filing an appeal.

15A NCAC 24A .0503 - The current rule refers to

the 15 day appeal period which we are changing to 60 days in .0502, therefore we are deleting reference to the 15 day appeal period. We are also creating a provision for holding Authorization Requests received while financial eligibility is being investigated until a decision about termination of eligibility is made.

**Comment Procedures:** All persons interested in these matters are invited to attend the public hearing. Written comments may be presented at the public hearing or submitted to John P. Barkley, Department of Justice, P.O. Box 629, Raleigh, NC 27602-0629, (919)733-4618. If you desire to speak at the public hearing, notify John P. Barkley at least 3 days prior to the public hearing. Oral presentation lengths may be limited depending on the number of people that wish to speak at the public hearing. Only persons who have made comments at a public hearing or who have submitted written comments will be allowed to speak at the Commission meeting. Comments made at the Commission meeting must either clarify previous comments or address proposed changes from staff pursuant to comments made during the public hearing process.

IT IS VERY IMPORTANT THAT ALL INTERESTED AND POTENTIALLY AFFECTED PERSONS, GROUPS, BUSINESSES, ASSOCIATIONS, INSTITUTIONS, OR AGENCIES MAKE THEIR VIEWS AND OPINIONS KNOWN TO THE COMMISSION FOR HEALTH SERVICES THROUGH THE PUBLIC HEARING AND COMMENT PROCESS, WHETHER THEY SUPPORT OR OPPOSE ANY OR ALL PROVISIONS OF THE PROPOSED RULES. THE COMMISSION MAY MAKE CHANGES TO THE RULES AT THE COMMISSION MEETING IF THE CHANGES COMPLY WITH G.S. 150B-21.2(f).

**CHAPTER 24 - GENERAL PROCEDURES  
FOR PUBLIC HEALTH PROGRAMS**

**SUBCHAPTER 24A - PAYMENT  
PROGRAMS**

**SECTION .0100 - GENERAL PROVISIONS**

**.0101 GENERAL**

(a) The purpose of this Subchapter is to establish uniform policies and procedures for the administration of all Department of Environment, Health, and Natural Resources' payment programs.

These rules are intended to facilitate efficient financial eligibility and payment mechanisms with a mutual goal of the Department and the providers to render appropriate services to eligible patients.

(b) In the event of conflict between the rules in this Subchapter and the rules adopted by the various payment programs, the rules of this Subchapter will control.

(c) The rules of this Subchapter shall not apply to the North Carolina Hemophilia Assistance Plan, 15A NCAC 21F .1100 or to the Home Health Program, 15A NCAC 16A .0200.

(d) Persons who wish to receive rule-making notices concerning the rules in this Subchapter must submit a written request to the Purchase of Medical Care Services Section, P.O. Box 27687, Raleigh, N.C. 27611-7687. The request must specify the calendar year during which the person wishes to receive the notices. A check for ten dollars (\$10.00) made payable to the N.C. Department of Environment, Health, and Natural Resources must be enclosed with each request to cover the cost of printing and mailing the notices for the year specified. The fee is non-refundable if there are no notices during the year.

*Statutory Authority G.S. 130A-5(3); 130A-124; 130A-127; 130A-129; 130A-205.*

## SECTION .0500 - QUALITY CONTROL

### .0502 TERMINATION OF FINANCIAL ELIGIBILITY

The Department shall take the following steps in order to terminate a person's financial eligibility which is based ~~upon~~ on incorrect information:

- (1) Notice shall be given to the applicant and the financial eligibility interviewer that the Department believes has determined that the financial eligibility form was contains established based on incorrect information that materially affected the person's financial eligibility presented on the financial eligibility form, the applicant is not financially eligible, and the Department has made a tentative decision to terminate financial eligibility.
- (2) ~~After the 15 day period, if the Department determines that financial eligibility shall be terminated, notice shall be given to the applicant, the interviewer and the provider that the Department has made a tentative decision to terminate financial eligibility. The applicant shall be given 15 days to request an appeal.~~

The applicant and the financial eligibility interviewer shall be given 15 days to provide additional information to show why eligibility should not be terminated.

- (3) ~~If no appeal is made within 15 days, financial eligibility shall be terminated. If information which proves that the applicant is financially eligible is not received by the Department within 15 days, financial eligibility shall be terminated. The applicant shall be given 60 days from the date of the notice of tentative decision to terminate financial eligibility to file an appeal. However,~~ The applicant may reapply for financial eligibility at any time if there is a change in family size, income, or deductions.

*Statutory Authority G.S. 130A-5(3); 130A-124; 130A-127; 130A-129; 130A-205.*

### .0503 EFFECT ON AUTHORIZATIONS AND AUTHORIZATION REQUESTS

(a) All authorizations will be honored by the Department, except that an authorization may will be cancelled ~~after a final decision to terminate upon termination of~~ financial eligibility if:

- (1) The applicant and the provider are notified of the authorization cancellation prior to the provision of the service. Authorizations ~~may will~~ be cancelled in part when only some of the services have been provided; and
- (2) The provider has not made financial commitments based upon the authorization.

(b) ~~Authorization requests for services to be provided after the 15 day appeal period which are received by the Department after a tentative decision to terminate financial eligibility and prior to a final decision in the matter will be held until a final decision is made received during the period of time that financial eligibility is being investigated will be held until a decision about termination of eligibility is made. If financial eligibility is terminated, all pending authorization requests will be denied.~~

*Statutory Authority G.S. 130A-5(3); 130A-124; 130A-127; 130A-129; 130A-205.*

## TITLE 21 - OCCUPATIONAL LICENSING BOARD

**Notice** is hereby given in accordance with G.S. 150B-21.2 that the North Carolina Board of Mortuary Science intends to amend rules cited as 21 NCAC 34A .0102 and .0201; adopt 21 NCAC 34D .0101 - .0103, .0201 - .0202, .0301 - .0304 and .0401 - .0404.

**The** proposed effective date of this action is April 1, 1993.

**The** public hearing will be conducted at 1:00 p.m. on February 15, 1993 at the Auditorium of State Highway Building, 1 South Wilmington Street, Raleigh, NC.

**Reason for Proposed Action:**

**21 NCAC 34A .0102** - G.S. 90, Article 13D, has expanded purpose of Board to include regulation of sale of preneed funeral contracts.

**21 NCAC 34A .0201** - G.S. 90-210.67 directs Board to set fees.

**21 NCAC 34D .0101** - G.S. 90-210.62(b) directs Board to approve preneed contract forms. Proposed Rule sets requirements for forms.

**21 NCAC 34D .0102** - G.S. 90-210.67(d) imposes per-contract fee. Board needs to make provision for refund of fee if contract not binding because insurance coverage denied.

**21 NCAC 34D .0103** - Board needs to inform sellers and purchasers of a typical fact situation under which a "preneed funeral contract" arises pursuant to definition in G.S. 90-210.60(5).

**21 NCAC 34D .0201** - Board needs to inform applicants of requirements for applications, renewals and display of preneed funeral establishment license.

**21 NCAC 34D .0202** - G.S. 90-210.67(a) requires Board to establish qualifications for and activities permitted under preneed sales license. Applicants need to know application requirements.

**21 NCAC 34D .0301** - Board needs to inform funeral homes in what form preneed records are to be kept for inspection.

**21 NCAC 34D .0302** - Board needs to inform funeral homes of contents of annual report to be filed with Board.

**21 NCAC 34D .0303** - Board needs to establish contents of and funeral home needs to know how to present certificate for obtaining funds to pay for funeral.

**21 NCAC 34D .0304** - G.S. 90-210.68(b) permits transfer of trust funds from one financial institution

to another. Rule is needed for procedure, including use of Board form.

**21 NCAC 34D .0401** - Definitions of terms needed, as used in succeeding Rules pertaining to Preneed Recovery Fund.

**21 NCAC 34D .0402** - G.S. 90-210.66(d) requires Board to adopt rules governing presentation of applications for reimbursement from fund.

**21 NCAC 34D .0403** - G.S. 90-210.66(d) requires Board to adopt rules governing processing applications for reimbursement from fund.

**21 NCAC 34D .0404** - G.S. 90-210.66(d) requires Board to adopt rules governing subrogation as to reimbursements from fund.

**Comment Procedures:** Interested persons may present statements, orally and in writing, at the public hearing and in writing prior to the hearing by mail addressed to Mr. Donald H. Carpenter, NC Board of Mortuary Science, Box 27368, Raleigh, NC 27611-7368.

## **CHAPTER 34 - BOARD OF MORTUARY SCIENCE**

### **SUBCHAPTER 34A - BOARD FUNCTIONS**

#### **SECTION .0100 - GENERAL PROVISIONS**

##### **.0102 PURPOSE OF BOARD**

The purpose and function of the Board are to examine, license and regulate the practice of funeral service, ~~and~~ the operation of crematories and the sale of preneed funeral contracts in North Carolina, pursuant to the authority granted by Articles 13A, ~~and~~ 13C and 13D, Chapter 90, General Statutes of North Carolina.

Statutory Authority G.S. 90-210.23(a); 90-210.50(a); 90-210.69(a).

**SECTION .0200 - FEES AND OTHER  
PAYMENTS**

**.0201 FEES AND PENALTIES**

(a) Fees for funeral service shall be as follows:

Establishment permit	
Application	\$ 250.00
Annual renewal	\$ 150.00
Late renewal penalty	\$ 100.00
Establishment reinspection fee	\$ 100.00
Courtesy card	
Application	\$ 75.00
Annual renewal	\$ 50.00
Out-of-state licensee	
Application	\$ 200.00
Embalmer, funeral director, funeral service	
Application, North Carolina resident	\$ 150.00
Application, non-resident	\$ 200.00
Annual renewal	
Embalmer	\$ 40.00
Funeral director	\$ 40.00
Funeral service	\$ 60.00
Reinstatement fee	\$ 50.00
Resident trainee permit	
Application	\$ 50.00
Annual renewal	\$ 35.00
Late renewal penalty	\$ 25.00
Duplicate license certificate	\$ 25.00
Chapel registration	
Application	\$ 150.00
Annual renewal	\$ 100.00

(b) Fees for crematories shall be as follows:

License	
Application	\$ 400.00
Annual renewal	\$ 150.00
Late renewal penalty	\$ 75.00
Crematory reinspection fee	\$ 100.00
Per-cremation fee	\$ 5.00

(c) Fees for preneed funeral contract regulation shall be as follows:

<u>Preneed funeral establishment license</u>	
<u>Application</u>	<u>\$ 100.00</u>
<u>Annual renewal</u>	<u>\$ 100.00</u>
<u>Preneed sales license</u>	
<u>Application</u>	<u>\$ 10.00</u>
<u>Annual renewal</u>	<u>\$ 10.00</u>

*Statutory Authority G.S. 90-210.23(a); 90-210.28; 90-210.48; 90-210.67(b), (c).*

## SUBCHAPTER 34D - PRENEED FUNERAL CONTRACTS

### SECTION .0100 - GENERAL PROVISIONS

#### .0101 APPROVAL OF CONTRACT FORMS

No preneed funeral contract form shall be approved by the Board unless it, with any attachments, meets the following requirements, insofar as they are applicable to the lawful, intended sales transaction:

- (1) Is written in clear, understandable language and is printed in easy-to-read type, size and style.
- (2) States or provides space for inserting the name, address and preneed funeral establishment license number of the contracting funeral establishment.
- (3) Provides space for inserting the names, addresses and Social Security numbers of the purchaser and contract beneficiary.
- (4) Provides space for a description of the merchandise and services purchased.
- (5) Discloses any penalties or restrictions, including geographical restrictions, on the delivery of merchandise and services.
- (6) States whether it is a standard or inflation-proof contract and summarizes, consistent with North Carolina law, the incidents of such type of contract.
- (7) Provides space for inserting the financial transaction.
- (8) Provides space for the purchaser to indicate, by the purchaser's signature or initials, the following:
  - (a) The purchaser's choice of trust-funded or insurance-funded contract.
  - (b) That the purchaser acknowledges that the funeral establishment will retain, and not deposit in trust, a stated percentage (not more than 10%) of the purchaser's payments.
  - (c) The purchaser's choice of revocable or irrevocable contract.
  - (d) That the purchaser acknowledges that the sale was made at the funeral establishment's place of business, so as to negate the cancellation rights connected with an off-premises sale.
- (9) Contains notice, in bold type, of the purchaser's right to cancel an off-premises sale.
- (10) Contains notice, in bold type, that if the

purchaser does not receive notification from the Board, within 30 days, that it has received a copy of the contract, the purchaser should notify the Board at its current, stated address and telephone number.

- (11) Explains the parties' rights and obligations, consistent with North Carolina law, with respect to contract revocation, default, the funeral establishment's retention of a portion of the purchase price free of the trust, and the substitution of funeral homes to perform the contract.
- (12) Contains a notice of the existence of the Board's preneed recovery fund.
- (13) Contains, or refers to an attachment containing, all funeral sales disclosures to consumers as required by federal and North Carolina law.

Statutory Authority G.S. 90-210.69(a); 90-210.62(b).

#### .0102 REFUND OF CONTRACT FEES

The preneed funeral contract fee, paid as required by G.S. 90-210.67(d), shall be refunded by the Board to the payor only in the event that, because the insurance company refuses to insure the proposed preneed funeral contract beneficiary, the preneed funeral contract does not become binding.

Statutory Authority G.S. 90-210.69(a).

#### .0103 INSURANCE-FUNDED CONTRACTS

A "preneed funeral contract," as defined in G.S. 90-210.60(5), is created when any person, partnership, corporation or association of individuals engaged in the business of providing funeral services or merchandise is named, with knowledge of being named, as a revocable or irrevocable beneficiary or co-beneficiary or assignee of a "prearrangement insurance policy," as defined in G.S. 90-210.60(4), regardless of whether specific funeral services or merchandise is selected. This example does not preclude the creation of insurance-funded preneed funeral contracts pursuant to other facts.

Statutory Authority G.S. 90-210.69(a).

## SECTION .0200 - LICENSING

### .0201 PRENEED FUNERAL ESTABLISHMENT LICENSE

(a) A funeral establishment wishing to apply for a preneed funeral establishment license shall submit to the Board, in addition to the information required by G.S. 90-210.67(a), its funeral establishment permit number issued pursuant to G.S. 90-210.25(d), type of business entity, whether it is authorized to transact business in North Carolina, whether it is solvent, whether there exist unsatisfied civil judgments against the applicant and copies of any, whether the applicant or any of its principals has been denied a license to engage in an occupation or had a license suspended, revoked or placed on probation, and whether any principal has been convicted of a crime involving fraud or moral turpitude.

(b) The Board may require an applicant to submit additional proof to satisfy the requirements of G.S. 90-210.67(a) and (b).

(c) The applicant shall submit, with its application, the names, preneed sales license numbers and telephone numbers of all preneed sales licensees who will sell preneed funeral contracts as employees or agents of the applicant. Any additions to or deletions from the list of names shall be reported to the Board, within 10 days of the change, as an amended application on an application form.

(d) The same Board form shall be used for the original application, annual renewal application and amended application.

(e) Preneed funeral establishment licenses shall not be transferable. Upon a transfer of ownership of a funeral establishment, the provisions of 21 NCAC 34B .0605 apply, and a new application for a preneed funeral establishment license shall be made to the Board within 30 days of the transfer. The application fee shall accompany the application, as in the case of initial applications.

(f) The license certificate shall be conspicuously displayed in the funeral establishment at the address to which it is issued.

*Statutory Authority G.S. 90-210.69(a); 90-210.67(a), (b).*

### .0202 PRENEED SALES LICENSE

(a) Subject to G.S. 90-210.69(c), holding a funeral director's license, issued by the Board, or a funeral service license, issued by the Board, is the qualification to be eligible for a preneed sales license.

(b) The preneed sales licensee may engage, under the preneed sales license, in all of the activities of "preneed funeral planning" as defined in G.S. 90-210.60(8). No preneed funeral planning activities shall be engaged in by anyone other than a preneed sales licensee. No preneed sales license is required for solely the sale of a prearrangement insurance policy.

(c) A licensed funeral director or funeral service licensee wishing to apply for a preneed sales license shall submit to the Board the applicant's name, address, telephone number, funeral director's or funeral service license number, name and address of the preneed funeral establishment licensee or licensees on whose behalf the applicant will sell preneed funeral contracts, and the applicant's employment or agency relationship with the licensee or licensees. If the applicant proposes to sell on behalf of more than one preneed funeral establishment licensee, the applicant shall disclose information to satisfy the requirement of G.S. 90-210.67(a) that the preneed funeral establishment licensees be related by ownership or contract.

(d) The Board shall issue to each preneed sales licensee a pocket card as certification of the preneed sales license. The preneed sales licensee shall carry the card while engaging in preneed funeral planning. The card shall indicate the names of the preneed funeral establishment licensees on whose behalf the preneed sales licensee is authorized to sell preneed funeral contracts, and if there is any change in the list of establishments on whose behalf the preneed sales licensee is authorized to sell, the preneed sales licensee shall make a new application for a preneed sales license and shall pay the application fee.

*Statutory Authority G.S. 90-210.69(a); 90-210.67(a), (c).*

## SECTION .0300 - OPERATIONS

### .0301 RECORD AND BOOKKEEPING REQUIREMENTS

(a) Each preneed funeral establishment licensee shall maintain at the address stated on its license a general file containing:

- (1) a copy of each of its license applications, including applications for license renewals;
- (2) copies of all preneed examination reports; and
- (3) copies of all annual reports to the Board.



(b) Each such licensee shall maintain, at the same address, files containing all preneed funeral contracts purchased. The files shall be maintained separately for outstanding contracts and for matured or cancelled contracts. The outstanding contract file shall include a copy of each preneed contract filed alphabetically or numerically. The matured or cancelled contract file shall contain a copy of each preneed contract, together with a copy of the certificate of performance, and shall be filed either chronologically or alphabetically by year.

(c) Each such licensee shall maintain, at the same address, the following records:

- (1) a contract register listing the purchaser's name and final disposition of the contract;
- (2) a separate cash journal or separate cash receipt book designated for preneed, showing all preneed payments collected;
- (3) an individual ledger for each contract purchaser showing the purchaser's and beneficiary's names, amount of the contract, amount paid on the contract, amount retained free of trust pursuant to G.S. 90-210.61(a)(2), deposits to trust, withdrawals from trust as permitted by law and the reasons therefor, interest on deposits, total amount of the trust, and amounts paid to insurance companies for insurance-funded contracts;
- (4) copies of bank statements and deposit slips from financial institutions in which trust funds are deposited, certificate of deposit records, including both principal and interest transactions and/or trust accountings; and
- (5) copies of applications for insurance, insurance policies, beneficiary designation documents and instruments of assignment.

(d) Individual ledgers and records of the depository financial institutions shall be balanced at least annually to ensure accuracy.

*Statutory Authority G.S. 90-210.69(a); 90-210.68(a).*

### **.0302 ANNUAL REPORT**

Each preneed funeral establishment licensee shall file an annual report with the Board. The report shall include the following:

- (1) the total number of standard and/or

inflation-proof trust-funded and insurance-funded preneed funeral contracts maintained by the licensee;

- (2) the number of contracts sold in the reporting period;
- (3) the number of contracts which expired, including contracts performed, revoked and transferred, in the reporting period;
- (4) the total year-end balance of all preneed trust accounts maintained at each financial institution; and
- (5) the total year-end balance of all insurance-funded preneed contracts written with each insurance company.

The annual report shall be filed not later than March 31 each year for the preceding year ending December 31.

*Statutory Authority G.S. 90-210.69(a); 90-210.68(a).*

### **.0303 CERTIFICATE OF PERFORMANCE**

(a) The certificate of performance or similar claim form as required by G.S. 90-210.64(a) shall be a form as prepared by the Board and shall require the following information: the names, addresses and preneed funeral establishment license numbers of the performing funeral establishment and the contracting funeral establishment; the name of the deceased beneficiary of the preneed funeral contract; the date of death and the county where the death certificate was or will be filed; the invoice amount; certification that the contract was or was not performed in whole or in part and how the funds will be applied; the name and address of the financial institution where the preneed trust funds are deposited and the trust account or certificate number; the name and address of the insurance company which issued the prearrangement insurance policy and the policy number; and the amount and the date of the payment by the financial institution or insurance company and to whom paid.

(b) The form shall be completed by each funeral establishment performing any services or providing any merchandise pursuant to the preneed funeral contract, or, if none are performed or provided, by the contracting funeral establishment. The form shall be presented to the financial institution or insurance company for payment. Within 10 days following its receipt of payment, any funeral establishment which is required to complete the form shall mail a copy to the Board.

Statutory Authority G.S. 90-210.69(a); 90-210.64(a); 90-210.68.

#### .0304 TRANSFER OF TRUST FUNDS

When, pursuant to G.S. 90-210.68(b), a preneed licensee directs a transfer of preneed funds to a substitute financial institution, the financial institution which is a party to the preneed funeral contract shall make the transfer directly and solely to the substitute financial institution and not mediate to the preneed licensee. The notification to the Board as required by G.S. 90-210.68(b) shall be made on a form provided by the Board, which shall indicate the transfer of the funds by the financial institution and their acceptance by the substitute financial institution and the agreement of the substitute financial institution to be bound by the preneed funeral contract and, if the contract is revocable, certification that the licensee has notified the purchaser of the intended transfer.

Statutory Authority G.S. 90-210.69(a); 90-210.68(b).

### SECTION .0400 - PRENEED RECOVERY FUND

#### .0401 DEFINITIONS

For the purposes of this section, the following definitions shall apply:

- (1) "Fund" shall mean the preneed recovery fund as established by G.S. 90-210.66.
- (2) "Applicant" shall mean a person who has suffered a reimbursable loss pursuant to G.S. 90-210.66.
- (3) "Reimbursable losses" are only those losses of money which meet the requirements of G.S. 90-210.66 and in which, as determined by the Board, the applicant has exhausted all viable means to collect the applicant's losses and has complied with this section. Reimbursable losses shall not include losses of spouses, children, parents, grandparents, siblings, partners, associates, employers and employees of the person or business entity causing the losses.

Statutory Authority G.S. 90-210.69(a); 90-210.66(c), (d), (f), (g).

#### .0402 APPLICATION FOR REIMBURSEMENT

(a) The Board shall furnish a form of application for reimbursement which shall require the

following minimum information:

- (1) The name and address of the applicant.
- (2) The name and address of the licensee under G.S. 90, Article 13D, who caused the alleged loss.
- (3) The amount of the alleged loss for which application for reimbursement is made.
- (4) A copy of any preneed funeral contract which was the basis of the alleged loss.
- (5) The date or period of time during which the loss was incurred.
- (6) A general statement of facts relative to the application.
- (7) All supporting documents, including copies of court proceedings and other papers indicating the efforts of the applicant to obtain reimbursement from the licensee, insurance companies or others.
- (8) A documentation of any receipt of funds in partial payment of the loss.

(b) The application form shall contain the following statement in boldface type: "The North Carolina General Assembly in G.S. 90-210.66 established the preneed recovery fund and directed the North Carolina Board of Mortuary Science to provide for its funding and administration. The establishment of the fund did not create or acknowledge any legal responsibility on the part of the Board for the acts, or failure to act, of persons, firms or corporations licensed by it. All reimbursements of losses from the fund shall be a matter of privilege in the sole discretion of the Board and not a matter of right. No applicant or member of the public shall have any right in the fund as a third-party beneficiary or otherwise."

(c) An application shall be filed in the office of the Board.

Statutory Authority G.S. 90-210.69(a); 90-210.66(a), (c), (d), (f), (g).

#### .0403 PROCESSING APPLICATIONS

(a) The Board in making investigation of all applications filed for reimbursement from the preneed recovery fund may require the attendance of and examine under oath all persons, including the alleged defalcating licensee, whose testimony it may require. A determination of the application shall be made by a majority vote of those present at a Board meeting at which a quorum is present. The Board may, in its discretion, afford the applicant a reconsideration of the application; otherwise, a rejection is final, and no further

consideration shall be given by the Board to the application or to another application based upon the same alleged facts.

(b) No more than 50% of the amounts received by the fund shall be available for disbursement for applications until a corpus of \$50,000.00 is created. Subject to the foregoing, the Board shall, in its discretion, determine the amount of loss, if any, for which the applicant should be reimbursed from the fund. In making such determination, the Board's considerations shall include:

- (1) The negligence, if any, of the applicant which contributed to the loss.
- (2) The hardship which the applicant suffered because of the loss.
- (3) The total amount of reimbursable losses of applicants on account of any one licensee or association of licensees.
- (4) The total amount of previous reimbursable losses for which total reimbursement has not been made and the total assets of the fund.
- (5) The total amount of insurance available to compensate the applicant for the loss.

(c) The Board may, in its discretion, allow further reimbursements in cases in which a loss has not been fully reimbursed.

(d) Before receiving a payment from the fund, the person who is to receive such payment or his or her legal representative shall execute and deliver to the Board a written agreement stating that in the event the reimbursed applicant or his or her estate ever receives any restitution from the licensee or from any other source, the reimbursed applicant or his or her estate shall repay the fund the restitution received or the amount of reimbursement from the fund, whichever is less.

Statutory Authority G.S. 90-210.69(a); 90-210.66(a), (c), (d), (g).

#### .0404 SUBROGATION

In pursuing a subrogation claim as authorized by G.S. 90-210.66(h), the Board may require the reimbursed applicant to execute a subrogation agreement, providing for, among other things, that the action may be brought in the name of the applicant. Upon commencement of an action by the Board pursuant to its subrogation rights, it shall notify the reimbursed applicant at his or her last known address in order that the applicant may join in the action if desired. Any amounts recovered by the Board in excess of the amount to which the fund is subrogated, less the Board's

actual costs of recovery, shall be paid to or retained by the reimbursed applicant as the case may be.

Statutory Authority G.S. 90-210.69(a); 90-210.66(d).

### TITLE 24 - INDEPENDENT AGENCIES

*Notice is hereby given in accordance with G.S. 150B-21.2 that the Safety and Health Review Board of North Carolina intends to amend rules cited as 24 NCAC 3 .0505 - .0506, .0602.*

*The proposed effective date of this action is April 1, 1993.*

*The public hearing will be conducted at 10:00 a.m. on February 15, 1993 at the N.C. State Bar Building, Council Chambers - 3rd Floor, 208 Fayetteville Street Mall, Raleigh, N.C.*

*Reason for Proposed Action: The purpose of the amendments to the rules are to: allow cross-appeals; define responsibilities for ordering transcripts and for sharing the cost of transcripts between cross-appellant; define time periods for filing briefs and the format of briefs for cross-appellants and to allow friend-of-the-court briefs.*

*Comment Procedures: Anyone wishing to comment on these proposed amendments to the rules should send comments to Doris Hinton at 121 West Jones Street, Raleigh, NC 27603 by February 12, 1993.*

### CHAPTER 3 - SAFETY AND HEALTH REVIEW BOARD OF NORTH CAROLINA

#### SECTION .0500 - HEARINGS

#### .0505 COURT REPORTERS: FEES: COST OF TRANSCRIPT OF TESTIMONY

(a) The court reporter's fees and the cost of the original transcript of testimony for depositions as provided in Rules .0504 and .0511 of this Section, shall be borne by the party which arranges for the reporter's appearance and each person who desires a copy of the transcript will be responsible for securing it and for its cost.

(b) In cases where no appeal has been effected,

the Review Board will arrange for and pay for the private court reporter's fees for each hearing. If a transcript is ordered by the hearing examiner or Board and no appeal has been effected, or if the Board directs review, the Board will also pay for preparation of the original transcript and persons desiring a copy of the transcript will be responsible for securing it and for its cost.

(c) ~~If an appeal is effected~~ a petition for review is filed, the court reporter's fees, cost of the original transcript, one copy for the Board, and ~~one~~ copy for the appellant will be paid for by the appellant and other persons desiring a copy of the transcript will be responsible for securing it and for its cost. If a cross-petition for review is filed, the cross-petitioner shall reimburse the petitioner for one-third of the cost of the court reporter's fees, original transcript, and copy for the Board.

*Statutory Authority G.S. 95-135.*

#### **.0506 TRANSCRIPT OF TESTIMONY**

(a) Hearings, including testimony and argument (on request) shall be transcribed verbatim. ~~After a decision has been rendered by the hearing examiner and appeal has been taken, three copies of the transcript of testimony taken at the hearing, duly certified by the reporter, shall be filed with the Board. If review is directed by the Board, the Board will order the transcript and notify the parties when it is filed with the Board. If a petition for review is filed, the petitioner shall, at the time of filing, order the transcript and ensure that one copy is filed with the Board. The Board will notify parties when the transcript is filed with the Board.~~

(b) The public proceedings conducted by the Review Board and by its hearing examiners may be recorded by an audio-tape recorder by any person in attendance. The Chairman of the Review Board, or the hearing examiner shall control the manner of any tape recording process to ensure that it is not disruptive to the proceeding.

(c) Should it become impossible or extremely impractical for the court reporter to prepare a transcript of the evidence because of mechanical failure, loss or destruction of tapes or notes, or for any other reason, it shall become the duty of the parties to prepare a summary of evidence from their trial notes and best recollection. The prevailing party, or the party designated by the hearing examiner, shall have 30 days from the date notice is sent to him by the hearing examiner or the Review Board in which to prepare and serve upon opposing party his proposed summary of

evidence. The opposing party shall review it and if he disagrees with any portion thereof, or believes that the summary is not complete, he shall have 20 days in which to serve upon the prevailing party any proposed revisions, including any deletions and additions. If the prevailing party agrees to such revisions, the two parties shall sign a certification that the summary of evidence is agreed by them to accurately reflect the substance of the testimony and other evidence presented at the hearing. If the parties cannot agree, their respective versions of the summary shall be submitted to the hearing examiner and he or she shall review the proposals, together with the hearing examiner's trial notes, and thereafter enter a ruling as to what constitutes the summary of evidence, which shall thereafter be treated for all purposes as the transcript of the proceedings.

(d) Errors in the transcript of the hearing may be corrected by the hearing examiner on his own motion, or on the motion of a party. Each correction will be made by hand with pen and ink and initialed by the hearing examiner, or the hearing examiner may sign and attach an errata sheet.

*Statutory Authority G.S. 95-135.*

### **SECTION .0600 - POST HEARING PROCEDURES**

#### **.0602 REVIEW: BRIEFS FOR REVIEW**

(a) Petitioning for review. Any member of the Board may direct that a decision of a hearing examiner be reviewed by the entire Board as a whole. Any party ~~may request review within 30 days, adversely affected or aggrieved by the decision of the hearing examiner (pursuant to Rule .0309 or .0601 of this Chapter) or by the decision of the Chairman of the Review Board (pursuant to Rule .0309 of this Chapter) may file a petition for review.~~ The petitioner or cross-petitioner must comply with applicable Rules .0505 and .0506 of this Chapter. If no direction for review or request petition for review is given effected within 30 days of from the filing of the hearing examiner's order with the Board, date on which the hearing examiner's or Chairman's decision is filed with the Board, such order decision shall become a the final order of the Review Board. A petition for review or cross-petition for review may be conditional; either may state that review is sought only upon the existence of an opposing party's petition for review. A cross-petition for review may be filed within seven days of notice from the opposing

party of its petition for review.

(b) Content of the petition. A petition for review or cross-petition for review shall concisely and precisely state the portion(s) of the decision for which review is sought; refer to the citations and citation items (for example, Citation 1, Item 3) for which review is sought; identify by number any fact or conclusion set forth by the hearing examiner which is not supported by a preponderance of the evidence or which is contended to constitute an error of law; and identify any error contended to be prejudicial or any instance which is contended to be an abuse of discretion.

(c) Procedure; briefs. A petition for review, or cross-petition for review, timely filed, shall be deemed granted upon receipt by the Review Board. All interested parties to the original hearing shall be notified of the date and the time and place of such hearing and shall be allowed to appear in person or by representative as previously defined. Parties on appeal to the Review Board shall file a brief of reasons and supporting authorities relied on. Failure to file a brief may result in judgment against the parties for failure to comply with these Rules. the original and three copies of the brief shall be filed with the Board. A party shall, prior to the statement of facts, designate in his brief those pages of the transcript relevant to each portion of the decision and order of the hearing examiner to which exception is taken. The purpose of this Rule is to require parties to notify the Review Board of any pages or parts of the transcript which are irrelevant to the decision before the Review Board, as well as to notify the Review Board of those pages and parts of the transcript which are relevant. A cross-petitioner shall file a single brief divided into two distinct sections: the first section shall respond to the petitioner's brief; the second section shall set forth issues on cross-appeal in accordance with this Rule. A petitioner's reply brief shall be limited to the issues raised in the second section of the cross-petitioner's brief.

(1) When review is directed by the Board, the Commissioner of Labor shall file the first brief within 30 days after being notified by the Board that the transcript of the hearing has been filed with the Board. Any opposing party shall then file its brief within 30 days of service of the Commissioner's brief.

(2) If a petition for review is filed, the petitioning party shall file the first brief within 30 days of being notified by the

Board that the transcript of the hearing has been filed with the Board. Any opposing party, including a cross-petitioner, shall file its brief within 30 days of service of the petitioning party's brief.

(3) If a cross-petition for review is filed, the petitioner for review shall file any reply brief within 15 days of service of the cross-petitioner's brief.

(4) If a petition for interlocutory review is filed and the hearing examiner or Board permits or orders the filing of briefs, the first brief must be filed by the petitioner within 15 days of notice that review is granted. Any opposing party shall file its brief within 15 days of service of the petitioning party's brief.

(5) The brief of an amicus curiae may be filed only by leave of the Review Board Chairman. The motion for leave shall identify the interest of the applicant and shall state the reasons why a brief of an amicus curiae is desirable. Any amicus curiae shall file its brief within the time allowed the party whose position the amicus will support.

Normally, review will be strictly limited to issues raised in the petition for review and cross-petition for review, or, if review is directed by the Board, review will normally be limited to issues upon which the hearing examiner passed judgment.

(d) Upon review of any decision of a hearing examiner, the Board may adopt, modify, or vacate the decision of the hearing examiner and notify the interested parties. The report, decision, or determination of the Board upon review shall be final unless further appeal is made to the court as provided in Rule .0605 of this Section.

*Statutory Authority G.S. 95-135.*

*The Rules Review Commission (RRC) objected to the following rules in accordance with G.S. 143B-30.2(c). State agencies are required to respond to RRC as provided in G.S. 143B-30.2(d).*

## **ADMINISTRATION**

### **Motor Fleet Management Division**

<i>1 NCAC 38 .0205 - Accident Reporting</i>	<i>RRC Objection 09/17/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed 10/15/92</i>

## **AGRICULTURE**

### **Structural Pest Control Division**

<i>2 NCAC 34 .0406 - Spill Control</i>	<i>RRC Objection 07/16/92</i>
<i>Agency Responded</i>	<i>No Action 08/20/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed 10/15/92</i>
<i>2 NCAC 34 .0603 - Waivers</i>	<i>RRC Objection 07/16/92</i>
<i>Agency Responded</i>	<i>No Action 08/20/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed 10/15/92</i>
<i>2 NCAC 34 .0902 - Financial Responsibility</i>	<i>RRC Objection 07/16/92</i>
<i>Agency Responded</i>	<i>No Action 08/20/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed 10/15/92</i>

## **ECONOMIC AND COMMUNITY DEVELOPMENT**

### **Banking Commission**

<i>4 NCAC 3E .0201 - Operation of other Business in same Office</i>	<i>RRC Objection 11/19/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed 11/19/92</i>

### **Community Assistance**

<i>4 NCAC 19S .0101 - Overview and Purpose</i>	<i>RRC Objection 10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed 11/19/92</i>
<i>4 NCAC 19S .0102 - Definition</i>	<i>RRC Objection 10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed 11/19/92</i>
<i>4 NCAC 19S .0103 - Waiver</i>	<i>RRC Objection 10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed 11/19/92</i>
<i>4 NCAC 19S .0202 - Prohibited Costs</i>	<i>RRC Objection 10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed 11/19/92</i>
<i>4 NCAC 19S .0401 - Distribution of Funds</i>	<i>RRC Objection 10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed 11/19/92</i>
<i>4 NCAC 19S .1101 - Grant Agreement</i>	<i>RRC Objection 10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed 10/15/92</i>

### **Departmental Rules**

<i>4 NCAC 1K .0103 - Eligible Applicants</i>	<i>RRC Objection 11/19/92</i>
<i>4 NCAC 1K .0204 - Discretionary Public Hearing by the Department</i>	<i>RRC Objection 11/19/92</i>

<i>4 NCAC 1K .0205 - Formal Application Procedures: Approval</i>	<i>RRC Objection</i>	<i>11/19/92</i>
<i>4 NCAC 1K .0206 - Formal Application Procedures: Denial</i>	<i>RRC Objection</i>	<i>11/19/92</i>
<i>4 NCAC 1K .0207 - Reimbursement of Extraordinary Expense</i>	<i>RRC Objection</i>	<i>11/19/92</i>
<i>4 NCAC 1K .0302 - Criteria for Making Necessary Findings</i>	<i>RRC Objection</i>	<i>11/19/92</i>

## **ENVIRONMENT, HEALTH, AND NATURAL RESOURCES**

### **Coastal Management**

<i>15A NCAC 7H .0308 - Specific Use Standards for Ocean Hazard Areas</i>	<i>RRC Objection</i>	<i>11/19/92</i>
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### **Departmental Rules**

<i>15A NCAC 1J .0204 - Loans from Emergency Revolving Loan Accounts</i>	<i>RRC Objection</i>	<i>06/18/92</i>
<i>15A NCAC 1J .0302 - General Provisions</i>	<i>RRC Objection</i>	<i>06/18/92</i>
<i>15A NCAC 1J .0701 - Public Necessity: Health: Safety and Welfare</i>	<i>RRC Objection</i>	<i>06/18/92</i>

### **Environmental Management**

<i>15A NCAC 2B .0216 - Outstanding Resource Waters</i>	<i>RRC Objection</i>	<i>11/19/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>11/19/92</i>
<i>15A NCAC 2H .0801 - Purpose</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>10/15/92</i>
<i>15A NCAC 2H .0803 - Definitions</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>10/15/92</i>
<i>15A NCAC 2H .0805 - Certification and Renewal of Certification</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Revised Rule</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Rule Returned to Agency</i>		<i>11/19/92</i>
<i>15A NCAC 2L .0107 - Compliance Boundary</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>10/15/92</i>
<i>15A NCAC 2O .0302 - Self Insurance</i>	<i>RRC Objection</i>	<i>06/18/92</i>

### **Wildlife Resources and Water Safety**

<i>15A NCAC 10I .0001 - Definitions</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Responded</i>	<i>No Action</i>	<i>11/19/92</i>

## **HUMAN RESOURCES**

### **Facility Services**

<i>10 NCAC 3R .3001 - Certificate of Need Review Categories</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>10/15/92</i>

### **Individual and Family Support**

<i>10 NCAC 42C .3601 - Administrative Penalty Determination Process</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>10/15/92</i>
<i>10 NCAC 42T .0001 - Definitions</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>10/15/92</i>
<i>10 NCAC 42T .0006 - Service Delivery</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Revised Rule</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>11/19/92</i>

### **Mental Health: General**

10 NCAC 14C .1115 - Funding Group Homes for Mentally Retarded Adults	RRC Objection	08/20/92
Agency Revised Rule	Obj. Removed	10/15/92
10 NCAC 14K .0216 - Waiver of Licensure Rules	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	10/15/92
10 NCAC 14T .0101 - Scope	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	10/15/92
10 NCAC 14T .0103 - Advance Care Directives	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	10/15/92

**Mental Health: Other Programs**

10 NCAC 18A .0125 - Definitions	RRC Objection	11/19/92
Agency Revised Rule	Obj. Removed	11/19/92
10 NCAC 18A .0132 - Decertification	RRC Objection	11/19/92
Agency Revised Rule	Obj. Removed	11/19/92
10 NCAC 18D .0117 - Purpose and Scope	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	10/15/92

**INDEPENDENT AGENCIES**

**N.C. Housing Finance Agency**

24 NCAC 1M .0202 - Eligibility	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0204 - Selection Procedures	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0205 - Administration	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0206 - Program Fees	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0301 - Goal and Objectives	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0302 - Eligibility Requirements	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0303 - Threshold Review Criteria	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0306 - Funding Commitment	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0401 - Goals and Objectives	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0402 - Eligibility Requirements	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0403 - Threshold Review Criteria	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0404 - Ranking Criteria	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1M .0405 - Agency Board Approval	RRC Objection	10/15/92
No Response from Agency	No Action	11/19/92
24 NCAC 1O .0101 - Purpose	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	11/19/92
24 NCAC 1O .0102 - Eligibility	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	11/19/92
24 NCAC 1O .0201 - Application Procedures	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	11/19/92
24 NCAC 1O .0202 - Selection Procedures	RRC Objection	10/15/92



<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>11/19/92</i>
<i>24 NCAC 10 .0203 - Administration</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>11/19/92</i>

**INSURANCE****Financial Evaluation Division**

<i>11 NCAC 11A .0602 - Licensure</i>	<i>RRC Objection</i>	<i>11/19/92</i>
<i>Agency Revised Rule</i>	<i>RRC Objection</i>	<i>11/19/92</i>

**Multiple Employer Welfare Arrangements**

<i>11 NCAC 18 .0019 - Description of Forms</i>	<i>RRC Objection</i>	<i>06/18/92</i>
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**Seniors' Health Insurance Information Program**

<i>11 NCAC 17 .0005 - SHIP Inquiries to Insurers and Agents</i>	<i>RRC Objection</i>	<i>06/18/92</i>
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**JUSTICE****General Statutes Commission**

<i>12 NCAC 8 .0506 - Declaratory Rulings</i>	<i>RRC Objection</i>	<i>10/15/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>11/19/92</i>

**LABOR****Occupational Safety and Health Act**

<i>13 NCAC 7C .0108 - Building Code</i>	<i>RRC Objection</i>	<i>09/17/92</i>
<i>Rule Returned to Agency</i>		<i>10/15/92</i>
<i>Agency Filed Rule with OAH</i>	<i>Eff.</i>	<i>10/22/92</i>
<i>13 NCAC 7C .0109 - Fire Prevention Code</i>	<i>RRC Objection</i>	<i>09/17/92</i>
<i>Rule Returned to Agency</i>		<i>10/15/92</i>
<i>Agency Filed Rule with OAH</i>	<i>Eff.</i>	<i>10/22/92</i>

**LICENSING BOARDS AND COMMISSIONS****Architecture**

<i>21 NCAC 2 .0108 - Fees</i>	<i>RRC Objection</i>	<i>11/19/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>11/19/92</i>

**Cosmetic Art Examiners**

<i>21 NCAC 14L .0301 - Applicants Licensed as Teachers in Other States</i>	<i>RRC Objection</i>	<i>11/19/92</i>
<i>21 NCAC 14L .0302 - Requirements for Obtaining a Teacher's License</i>	<i>RRC Objection</i>	<i>11/19/92</i>

**Dietetics/Nutrition**

<i>21 NCAC 17 .0016 - Violations, Complaints, Subsqnt Board Action, &amp; Hearings</i>	<i>RRC Objection</i>	<i>11/19/92</i>
<i>Agency Revised Rule</i>	<i>Obj. Removed</i>	<i>11/19/92</i>

**Professional Engineers and Land Surveyors**

21 NCAC 56 .0501 - Requirement for Licensing	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	10/15/92
21 NCAC 56 .0502 - Application Procedure: Individual	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	10/15/92
21 NCAC 56 .0701 - Rules of Professional Conduct	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	10/15/92
21 NCAC 56 .1603 - Classification of Surveys	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	10/15/92
21 NCAC 56 .1604 - Mapping Requirements	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	10/15/92
21 NCAC 56 .1605 - Classification of Topographic Surveys	RRC Objection	10/15/92
Agency Revised Rule	Obj. Removed	10/15/92

## **PUBLIC EDUCATION**

### **Elementary and Secondary Education**

16 NCAC 6C .0206 - Consortium-Based Programs	RRC Objection	11/19/92
Agency Revised Rule	Obj. Removed	11/19/92

## **REVENUE**

### **Individual Income, Inheritance and Gift Tax Division**

17 NCAC 3B .0401 - Penalties	RRC Objection	08/20/92
17 NCAC 3B .0402 - Interest	RRC Objection	08/20/92

### **Individual Income Tax Division**

17 NCAC 6B .0107 - Extensions	RRC Objection	08/20/92
17 NCAC 6B .0115 - Additions to Federal Taxable Income	RRC Objection	08/20/92
17 NCAC 6B .0116 - Deductions from Federal Taxable Income	RRC Objection	08/20/92
17 NCAC 6B .0117 - Transitional Adjustments	RRC Objection	08/20/92
17 NCAC 6B .3406 - Refunds	RRC Objection	08/20/92

## **TRANSPORTATION**

### **Division of Highways**

19A NCAC 2B .0164 - Use of Right of Way Consultants	RRC Objection	09/17/92
Agency Revised Rule	Obj. Removed	10/15/92
19A NCAC 2B .0165 - Asbestos Contracts with Private Firms	RRC Objection	08/20/92
Agency Revised Rule	Obj. Removed	10/15/92

***This Section of the Register lists the recent decisions issued by the North Carolina Supreme Court, Court of Appeals, Superior Court (when available), and the Office of Administrative Hearings which invalidate a rule in the North Carolina Administrative Code.***

**1 NCAC 5A .0010 - ADMINISTRATIVE PROCEDURES**

Thomas R. West, Administrative Law Judge with the Office of Administrative Hearings, declared two portions of Rule 1 NCAC 5A .0010 void as applied in *Stauffer Information Systems, Petitioner v. The North Carolina Department of Community Colleges and The North Carolina Department of Administration, Respondent and The University of Southern California, Intervenor-Respondent* (92 DOA 0666).

**15A NCAC 19A .0202(d)(10) - CONTROL MEASURES - HIV**

Brenda B. Becton, Administrative Law Judge with the Office of Administrative Hearings, declared Rule 15A NCAC 19A .0202(d)(10) void as applied in *ACT-UP TRIANGLE (AIDS Coalition to Unleash Power Triangle), Steven Harris, and John Doe, Petitioners v. Commission for Health Services of the State of North Carolina, Ron Levine, as Assistant Secretary of Health and State Health Director for the Department of Environment, Health, and Natural Resources of the State of North Carolina, William Cobey, as Secretary of the Department of Environment, Health, and Natural Resources of the State of North Carolina, Dr. Rebecca Meriwether, as Chief, Communicable Disease Control Section of the North Carolina Department of Environment, Health, and Natural Resources, Wayne Bobbitt Jr., as Chief of the HIV/STD Control Branch of the North Carolina Department of Environment, Health, and Natural Resources, Respondents* (91 EHR 0818).

*This Section contains the full text of some of the more significant Administrative Law Judge decisions along with an index to all recent contested cases decisions which are filed under North Carolina's Administrative Procedure Act. Copies of the decisions listed in the index and not published are available upon request for a minimal charge by contacting the Office of Administrative Hearings, (919) 733-2698.*

### KEY TO CASE CODES

ABC	Alcoholic Beverage Control Commission	DST	Department of State Treasurer
BDA	Board of Dental Examiners	EDC	Department of Public Instruction
BME	Board of Medical Examiners	EHR	Department of Environment, Health, and Natural Resources
BMS	Board of Mortuary Science	ESC	Employment Security Commission
BOG	Board of Geologists	HAF	Hearing Aid Dealers and Fitters Board
BON	Board of Nursing	HRC	Human Relations Committee
BOO	Board of Opticians	IND	Independent Agencies
CFA	Commission for Auctioneers	INS	Department of Insurance
COM	Department of Economic and Community Development	LBC	Licensing Board for Contractors
CPS	Department of Crime Control and Public Safety	MLK	Milk Commission
CSE	Child Support Enforcement	NHA	Board of Nursing Home Administrators
DAG	Department of Agriculture	OAH	Office of Administrative Hearings
DCC	Department of Community Colleges	OSP	Office of State Personnel
DCR	Department of Cultural Resources	PHC	Board of Plumbing and Heating Contractors
DCS	Distribution Child Support	POD	Board of Podiatry Examiners
DHR	Department of Human Resources	SOS	Department of Secretary of State
DOA	Department of Administration	SPA	Board of Examiners of Speech and Language Pathologists and Audiologists
DOJ	Department of Justice	WRC	Wildlife Resources Commission
DOL	Department of Labor		
DSA	Department of State Auditor		

CASE NAME	CASE NUMBER	ALJ	FILED DATE
Sandra C. Walker v. Department of Human Resources, Murdoch Center	90 OSP 0254	Nesnow	12/02/92
Donald W. Osborne v. North Carolina State University	91 OSP 0556	Becton	12/02/92
Bettie G. Person v. DHR, Division of Social Services, CSE	91 CSE 1181	Morgan	12/10/92
Anthony I. Somme v. DHR, Division of Social Services, CSE	91 CSE 1246	Mann	12/14/92

**CONTESTED CASE DECISIONS**

<b>CASE NAME</b>	<b>CASE NUMBER</b>	<b>ALJ</b>	<b>FILED DATE</b>
Todd C. Snead v. DHR, Division of Social Services, CSE	91 CSE 1290	Morrison	12/10/92
Steve Andrew Sloan v. DHR, Division of Social Services, CSE	92 CSE 0020	Gray	12/10/92
Jeanette Sheppard v. DHR, East Carolina University	92 OSP 0416	Morgan	12/08/92
Alonza Mitchell t/a Flavor, 5307 Market St., Wilmington, NC 28405 v. Alcoholic Beverage Control Commission	92 ABC 0496	Mann	12/11/92
Brenda Bowers, Bowers Day Care #2 v. DHR, Day Care Section	92 DHR 0603	Mann	12/02/92
John L. Bess v. DHR, Division of Social Services, CSE	92 CSE 0609	Reilly	12/14/92
Sylvia S. Pinyan DI# 00962/SSN 107-20-6984 v. Bd of Trustees of the Teachers' & St Emp Retirement Sys	92 DST 0686	Mann	12/07/92
Gerlene Locklear (Brayboy) v. DHR, Division of Social Services, CSE	92 DCS 0751	Nesnow	12/07/92
Alcoholic Beverage Control Commission v. Calvin Shackelford, T/A Shack's Place	92 ABC 0777	Gray	12/15/92
Britthaven, Inc. d/b/a Britthaven of Charlotte v. DHR, Division of Facility Services, Licensure Section	92 DHR 0853	Morrison	12/09/92
Anthony Dwayne Turman v. N.C. Private Protection	92 DOJ 1048	West	12/14/92

STATE OF NORTH CAROLINA

COUNTY OF FORSYTH

IN THE OFFICE OF  
ADMINISTRATIVE HEARINGS  
92 DST 0686

SYLVIA S. PINYAN,  
DI# 00962/SSN 107-20-6984,

Petitioner,

v.

THE BOARD OF TRUSTEES OF THE  
TEACHERS' AND STATE EMPLOYEES'  
RETIREMENT SYSTEM,

Respondent.

RECOMMENDED DECISION

This contested case was heard before Julian Mann, III, Chief Administrative Law Judge, on October 26, 1992, in the New County Building, Washington Courtroom, High Point, North Carolina.

APPEARANCES

For Petitioner:

Sylvia S. Pinyan  
4447 Thomasville Road  
Winston-Salem, North Carolina 27107  
Petitioner - Pro Se

For Respondent:

Alexander McC. Peters  
Associate Attorney General  
N. C. Department of Justice  
P.O. Box 629  
Raleigh, North Carolina 27602-0629  
Attorney for Respondent

WITNESSES

For Petitioner:

Sylvia S. Pinyan, Petitioner

For Respondent:

J. Marshall Barnes, III

EXHIBITS

For Petitioner:

Petitioner's Exhibit #1, 2

For Respondent:

Respondent's Exhibit #1, 2, 3 and 4

ISSUE

Whether or not Respondent acted improperly or otherwise than as required by law in offsetting Petitioner's benefits from the disability income plan?

Based upon the greater weight of the admissible evidence, the undersigned makes the following:

**FINDINGS OF FACT**

1. The Office of Administrative Hearings has jurisdiction over this contested case pursuant to Chapters 135 and 150B of the North Carolina General Statutes.

2. The Petitioner is a citizen and resident of Forsyth County, North Carolina.

3. The Petitioner was previously employed by the Davidson County Schools as a learning disabled/emotionally handicapped teacher.

4. The Petitioner was placed on long term disability by Respondent's medical board effective August 7, 1990.

5. At all times relevant herein, Petitioner was eligible to receive federal Social Security retirement benefits from the Social Security Administration.

6. On or about October 30, 1991, Respondent received an Attorney General's opinion authored by Norma S. Harrell, as to the correct interpretation of G.S. 135-106(b). Ms. Harrell interprets for the Respondent the following: (Respondent's Exhibit #1)

"...the test is not whether the individual is actually receiving the social security benefit. It is whether he could or would be entitled to it. Therefore, a person who is age 62 and eligible for a primary social security benefit must have his disability benefit reduced by the amount of the primary social security benefit to which he would be entitled, regardless of whether he has actually applied for received the social security benefit."

7. Based upon the Attorney General's opinion, on or about December 10, 1991, Respondent notified Petitioner of its intention to offset Petitioner's benefits as follows: (Respondent's Exhibit #2)

"Our records indicate that you have attained 62 years of age, however, at present our records do not indicate that you are in receipt of social security benefits. Therefore, it will be necessary for you to provide us a Statement from the Social Security Administration as to the amount of social security benefit you would have been entitled to receive at age 62."

8. Upon receipt of the foregoing correspondence, Petitioner, who was at all times eligible to receive the long term retirement benefit from the Social Security Administration, applied for social security retirement benefits. Petitioner began to receive the benefit from the Federal Social Security Retirement System in March, 1992.

9. On or about March 4, 1992, the Respondent notified the Petitioner of Respondent's intention to recoup \$655.00: (Correspondence - Respondent's Exhibit #3)

"Based on information you have provided, we have determined that your long-term disability benefits should have been reduced by the age 62 social security benefit you would be entitled to receive. We have estimated that, effective January 1, 1992, your benefit should have been offset by \$655.00. As your benefits were not reduced by the social security until February, 1992, we have determined that you have been overpaid long-term disability benefits in the amount of \$655.00.

The provisions of the plan require you to refund any overpayments. Therefore, you should forward your check or money order as soon as possible for \$655.00 to the North Carolina Employee Disability Fund in care of the Department of State Treasurer, 325 North Salisbury Street, Albemarle Building, Raleigh, North Carolina 27603-1388."

10. On or about April 13, 1992, Respondent notified Petitioner of Respondent's intention to recoup overpayment in monthly installments by correspondence quoted in part: (Respondent's Exhibit #3)

"Per our agreement, we will begin deducting \$72.78 from your monthly benefit in repayment of your outstanding balance. This deduction will begin with your benefit due April 24, 1992 and will continue for approximately 9 months. No interest will be charged on your outstanding balance."

11. Petitioner filed her contested case to dispute the Respondent's actions in making deductions from her State Retirement Disability Income but did not dispute Respondent's interpretation of G.S. 135-106(b) as to the setoff of benefits.

Based on the foregoing Findings of Fact, the undersigned Chief Administrative Law Judge makes the following:

CONCLUSIONS OF LAW

1. The Office of Administrative Hearings has jurisdiction over this contested case pursuant to Chapters 135 and 150B of the North Carolina General Statutes.

2. That at all times relevant herein, Petitioner was eligible to receive a primary Social Security Retirement benefit.

3. At all times relevant hereto, the Petitioner was receiving from Respondent a long term disability benefit pursuant to G.S. 135-106.

4. G.S. 135-106(b) mandates that Petitioner's long term disability benefit be reduced "by an amount, as determined by the Board of Trustees, equal to a primary Social Security retirement benefit to which the beneficiary might be entitled." (emphasis added)

5. Inasmuch as the Petitioner received from the Respondent a long term retirement disability benefit which was not setoff by Petitioner's Social Security retirement benefit for which she was eligible to receive, Respondent was entitled to seek a refund from the Petitioner in the amount of the overpayment.

6. Petitioner was advised of Respondent's intention to reduce Petitioner's benefit by way of correspondence mailed directly to Petitioner on or about December 10, 1991. Although the notice of the intention to terminate the benefits was brief, Petitioner was presented the opportunity to contest the determination by contacting the Member Services Section at the telephone number listed. Petitioner was accorded pre-termination procedural due process.\*

7. Inasmuch as Petitioner was given an opportunity to file a contested case to contest the reduction of benefits through a hearing at the Office of Administrative Hearings, Petitioner was accorded post-termination procedural due process.

8. Petitioner did not object at the hearing to the legality of Respondent's interpretation of G.S. 135-106(b) but only in the manner and procedure employed by Respondent to reduce Petitioner's long term disability benefits.

Based upon the foregoing Findings of Fact and Conclusions of Law, the undersigned makes the following:

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\*Although the pre-termination notice may be sufficient in law, such a change in the interpretation of the controlling statute does not appear to grant sufficient time for the affected class to which Petitioner belonged to apply and receive the Social Security retirement benefit to which they were actually entitled.



**RECOMMENDED DECISION**

That the Respondent affirm its decision to reduce Petitioner's long term disability benefit pursuant to G.S. 135-106(b) and that any overpayment resulting to the Petitioner be recouped from the Petitioner as provided by law.

**ORDER**

It is hereby ordered that the agency serve a copy of the final decision on the Office of Administrative Hearings, P.O. Drawer 27447, Raleigh, N. C. 27611-7447, in accordance with North Carolina General Statute 150B-36(b).

**NOTICE**

The agency making the final decision in this contested case is required to give each party an opportunity to file exceptions to this recommended decision and to present written arguments to those in the agency who will make the final decision. G.S. 150B-36(a).

The agency is required by G.S. 150B-36(b) to serve a copy of the final decision on all parties and to furnish a copy to the parties' attorney of record and to the Office of Administrative Hearings.

The agency that will make the final decision in this contested case is The Board of Trustees of the Teachers' and State Employees' Retirement System.

This the 7th day of December, 1992

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Julian Mann, III  
Chief Administrative Law Judge

STATE OF NORTH CAROLINA  
COUNTY OF MECKLENBURG

IN THE OFFICE OF  
ADMINISTRATIVE HEARINGS  
92 DHR 0853

BRITTHAVEN, INC. d/b/a BRITTHAVEN OF  
CHARLOTTE.

Petitioner,

v.

NORTH CAROLINA DEPARTMENT OF HUMAN  
RESOURCES, DIVISION OF FACILITY SERVICES,  
LICENSURE SECTION,

Respondent.

**RECOMMENDED DECISION  
BASED ON STIPULATED FACTS**

This contested case came on for hearing before the undersigned based upon stipulated facts and affidavits submitted by the parties. Petitioner Britthaven, Inc. d/b/a Britthaven of Charlotte (hereinafter "Britthaven") and Respondent North Carolina Department of Human Resources, Division of Facility Services, Licensure Section (hereinafter "Licensure Section" or the "Agency"). Those stipulations and affidavits have previously been filed with this office.

### ISSUES

1. Whether the Licensure Section properly and correctly imposed administrative penalties upon Britthaven for alleged incidents of failure to provide adequate care, treatment and services to patients.
2. If so, whether the amounts of the administrative penalties are reasonable.

### JURISDICTION

1. The parties are properly before the Office of Administrative Hearings, and the Office of Administrative Hearings has jurisdiction over the parties and over the subject matter of this contested case hearing.
2. The parties have been correctly designated, and there are no issues as to nonjoinder or misjoinder of parties. The parties are not aware of any other person seeking to intervene.
3. The Administrative Law Judge is properly designated and appointed and that the parties are unaware of any reason for which he should be disqualified.

### BURDEN OF PROOF

The burden of going forward with evidence in the burden of persuasion lie with Respondent. In order to prevail, Respondent has the burden to prove by the greater weight of the evidence that it properly and correctly imposed administrative penalties upon Petitioner for alleged incidents of failure to provide adequate care, treatment and services to patients, and that the amounts of the administrative penalties, if warranted, are reasonable.

**FINDINGS OF FACTS**

1. Petitioner Britthaven is a nursing home located in Charlotte, Mecklenburg County, North Carolina.

2. Respondent Licensure Section is the agency empowered pursuant to N.C.G.S. §131E-129, to impose administrative penalties upon nursing homes located in North Carolina.

3. On August 6, 1991, complaint investigators with the Licensure Section visited Britthaven for the purpose of investigating a report of possible deviations from statutes and regulations governing the licensure and operation of nursing homes.

4. Based upon that investigation, complaint investigators made recommendations for administrative action with regard to two patients.

5. The investigators' recommendations were submitted to an Internal Review Committee, comprised of three staff members of the Licensure Section, which on December 11, 1991, recommended that the Licensure Section assess Britthaven two Type B-2 administrative penalties, in the amount of \$50 each, for alleged violations based upon their conclusion that while there had been violations of the Nursing Home Patients Bill of Rights and applicable regulations, a causal connection could not be established between the facility's actions and the patients' conditions.

6. The Internal Review Committee's recommendation was submitted to the Agency's Penalty Review Committee ("PRC") which on January 16, 1992, recommended each penalty be increased to a Type A-1 \$250 penalty, for a total penalty amount of \$500.

7. PRC members voting at the January 16, 1992, meeting to increase in the penalty amount were Albert Thompson, David Donovan, Stewart Vick, and Alfred Boyles. PRC members voting against the recommendation to increase the penalty were Rebecca Dennis Olson, Gerald Cox and Edward Hart.

8. On February 10, 1992, the Licensure Section adopted the PRC's recommendation and imposed a \$500 administrative penalty upon Britthaven by letter from Jesse S. Goodman, Assistant Director, Licensure and Certification to Elsie J. Kevas, Administrator, Britthaven of Charlotte.

9. By letter dated April 22, 1992, Mr. Goodman advised Ms. Kevas that the Licensure Section was rescinding the administrative penalty and resubmitting the information regarding the penalty to the PRC for consideration at its meeting on May 21, 1992.

10. On June 18, 1992, the PRC recommended that each penalty be increased to a Type A-1 \$250 penalty.

11. PRC members voting at the June 18, 1992 meeting to increase the penalty amount were Albert Thompson, Rebecca Dennis Olson, David Donovan, Gayle Fleming and Alfred Boyles. PRC members voting against the recommendation to increase the penalty were Gerald Cox, Edward Hart and Stewart Vick.

12. Mr. Goodman accepted the June 18, 1992 recommendation of the Penalty Review Committee and imposed an administrative penalty in the amount of \$500 upon Britthaven by letter to Elsie J. Kevas dated June 26, 1992.

13. Britthaven timely appealed the imposition of the administrative penalty by Petition for Contested Case Hearing filed July 23, 1992.

14. On November 12, 1992, Britthaven filed a Motion for a Recommended Decision in the nature of Summary Disposition. On November 30, 1992, Britthaven filed a Motion to Dismiss with regard to the

second patient for which the agency issued an administrative penalty. Britthaven withdraws those motions.

**Patient #1 ("B.C.")**

15. Patient #1 ("B.C.") was a 79 year old resident who was readmitted to the facility on July 16, 1991, after an eight-day period of hospitalization where she was treated for bullous pemphigus and congestive heart failure. Her hospital diagnoses included: cerebral vascular accident with right hemiplegia, hypertension, atrial fibrillation, Brady arrhythmias, renal failure and syphilis (treated). Treatment of the pemphigus with Prednisone was continued after readmission to the facility.

16. On July 18, 1991, B.C.'s condition deteriorated, culminating in her death at 3:40 p.m. The course of events were documented in the nurse's notes as follows:

0600 - A quiet night - respiration rapid - No complaints. Alert and responsive - turned and positioned every 2 hours. No request for Oxygen. T96.7-P72-R28-BP 120/70

10: 15 a.m. - Alert and responsive, color good, skin w/d to touch. Resp. rapid @ 24-26. BP120/70 P88 T97.4. Patient unable to assist with care. Naps off and on, repositioned every 2 hours and as needed. SR Call light within reach. Skin remains very dry. Lotion as order. Lesion dried increased. Spoon fed, ate 100%. Inc of BtBn changes prn. s c/o on S.O.D. noted.

10:45 a.m. - Patient noted to be dyspneic. Order received for Oxygen at 2 liters/minute prn.

2:50 p.m. - CNA found patient cold and clammy, had to change patient's entire bed. BP 80/60 T96 P unable to feel @ etc. R-38 rapid. Patient alert and responsive to stimuli. Dr. Cynn notified waiting for return call.

3:00 p.m. - Tried to contact Dr. Cynn again. Nurse states, "I'm going to beep him." Patient chest sounds very congested. Unable to get a pulse.

3:40 p.m. - LPN found patient with no detectable respiration, no palpable pulse (radial or carotid) unable to auscultate BP. CPR started immed. by LPN and RN with board under back. 911 called by nurse. CPR continued until emergency crew arrived. Family member was called by staff with report of patient's condition. Message left with husband of responsible party. Emergency crew continued emergency measures were unable to detect any vital signs. Noted dilated pupils. Call placed to CMH and permission received to declare patient expiration.

4:10 p.m. - Attempt to call family members unsuccessful. Call placed to funeral home, they stated they knew the family and would make an attempt to locate them.

4:35 p.m. - Call placed to granddaughter in Wadesboro. Will have responsible party call us back.

4:10 p.m. - late entry - call placed to Dr. with report of patient's expiration.

4:45 p.m. - R.D., patient's sister called and gave permission to release the body to Smith Funeral Home, Wadesboro.

4:50 p.m. - Funeral home was called to pick up body.

6:30 p.m. - Funeral home came to facility to transport body to Wadesboro, Smith Funeral Home.

17. In addition to notations made in the nursing notes regarding B.C., additional measures were taken to care for this patient on July 18, 1991, between 7:30 a.m. and 3:40 p.m.

Specifically, the following measures were taken:

7:30 a.m. Blood pressure, temperature, and other vital signs taken, bed bath;  
8:00 a.m. Spoon feeding breakfast;  
10:00 a.m. Vital signs taken, patient assessed;  
10:35 a.m. Patient repositioned;  
12:00 noon Ampicillin administered;  
12:40 p.m. Vital signs taken, spoon fed lunch;  
1:00 p.m. Niacinamide given and magic mouthwash swish and swallow done;  
2:00 p.m. Vital signs taken;  
2:45 p.m. Vital signs taken;  
3:00 - 3:15 p.m. On-coming charge nurse made routine rounds.

18. Patient B.C.'s room was only 2 patient rooms from the nurse's station. She was being constantly monitored during the entire day on July 18, 1991, prior to her death at 3:40 p.m.

**Patient #2 ("W.J.")**

19. Patient #2 ("W.J.") was an 80 year old male who was readmitted to Britthaven on May 27, 1991 after a ten day hospitalization at Mercy Hospital in Charlotte including a stay in the Intensive Care Unit. He had a history of decompensated congestive heart failure, pulmonary embolus, deep vein thrombosis, and while in the hospital on May 18, 1991, he had a respiratory arrest, secondary to hypoxemia and was resuscitated. According to the hospital discharge summary, several times in the past W.J. had documented pulmonary embolus.

20. Upon return to Britthaven, W.J. was documented to be alert and oriented. For the next 21/2 days he remained stable on oxygen at 2 liters per minute, with temperatures 96.4° to 99.4° F, pulses 58 to 80, respirations 18 to 48, and blood pressures 120/60 to 156/80. He received Lasix 40mg, Digoxin .25mg, and Coumadin 5mg every day.

21. Beginning at 4:00 p.m. on May 30, 1991, patient W.J.'s nurses notes were as follows:

1600 hrs. - pt. condition remains unchanged, guarded, Oxygen per nasal canal at 2 liters per min. in progress. Position turned every 2 hr. Skin warm and dry; responsive to stimuli. Digs. P. O.:intake poor, unable to swallow on his own. Right side of mouth twisted, BP124/16, P64, R22, temp. 99.4.

2100 hrs. - Pt. unresponsive. Vital signs remains stable, BP/114/70, P. 60,R. 16 Unable to consume diet self. Not swallowing. Food holding in his mouth. Mouth care given by staff and feedings by staff.

2315 hrs. - Condition unchanged. Remains guarded. Oxygen via nasal cannule at 2 liters/minute. Skin cool and moist to touch. Respirations shallow.

2400 hrs. - No changes noted, respirations remain shallow.

5/31/91

0040 hrs. - Patient found unresponsive. Night charge nurse was called. Vital signs were taken. None present. Dr. Richardson's answering service was called by RN on duty.

0100 hrs. - No call received from Dr. Richardson. Answering service called again.

0110 hrs. - Dr. Richardson returned call. Stated her answering service did not contact her previously (at 0040). Asked for orders. Dr. Richardson suggested I call the DON and ask for facility procedure and act accordingly. DON notified of situation. Suggestion made to send pt. to hospital ER to be pronounced. Dr. Richardson notified of this. Stated that she would sign death certificate in A.M. 911 called. CPR initiated. Paramedic and 911 responded. Carried out necessary procedures for

present situation.

0230 hrs. - Family was notified and changed funeral home to Beasley's.

0400 hrs. - Body released to Beasley's Funeral Home.

22. On May 30, 1991, at 11:00 p. m., Edith Williams, R.N., the nurse in charge of the 11:00 p.m. to 7:00 a.m. shift, reviewed the condition of the patients with Loretta O'Malley, the nurse in charge of the 3:00 p.m. to 11:00 p.m. shift.

23. As they conducted their shift rounds, Ms. O'Malley specifically pointed out to Ms. Williams the condition of patient W.J. in room 24-A. They observed W.J. carefully because Ms. O'Malley felt that he was the sickest patient in the building on that evening. When they visited him in his room, his respirations were regular and appeared unlabored, and his pulse was strong and regular. His extremities were cool to the touch but they had been so for a number of days. Basically, his condition appeared to Ms. Williams to be the same as on previous evenings since he returned from the hospital. Ms. O'Malley stated that his condition appeared to be unchanged since she had last monitored him at 10:00 p.m.

24. After they completed their shift rounds, Ms. Williams began to monitor and assess other patients in the SNF wing, who were also in critical condition. She received no further information regarding W.J.'s condition until some time after 12:40 a.m., at which time, Mary Caldwell, L.P.N., advised her that during a monitoring visit W.J. had no respiration or pulse.

25. W.J. had been seriously ill for some period of time. He had been in and out of the hospital several times during the months prior to his expiration.

26. Respondent's nurse consultants contacted the North Carolina Board of Nursing for investigation regarding their findings.

27. With regard to patient W.J., the North Carolina Board of Nursing issued a reprimand to Mary Caldwell, L.P.N., for failure to initiate resuscitative measures when she found him to be without respirations or heartbeat. The Board of Nursing determined that no action should be taken against Edith Williams, R.N., the supervisor R.N. on that shift, or any other nurse, with regard to the care of patient W.J. No citations were made by the Board of Nursing regarding patient B.C., or regarding nursing assessment of either patient.

28. The Agency's internal guidelines define a Type A-1 violation as "[o]ne violation involving one patient with substantial risk of death or serious physical harm."

29. Agency internal guidelines define a Type B-2 violation as "[o]ne violation involving one or more patients put at risk with minimal or potential impact on patient health, safety or welfare."

30. With the exception of the administrative penalty which is the subject of this contested case, the Agency has noted no violations of licensure statutes or rules at the Britthaven facility warranting an administrative penalty or other negative sanctions.

31. Following receipt of the Agency's Report of Survey dated September 13, 1991, reporting on the August 6, 1991, complaint investigation, Britthaven submitted a Plan of Correction to the Agency on September 30, 1991, providing that all deficiencies noted would be adequately addressed and corrected by October 11, 1991. The Agency accepted that Plan of Correction and requested no changes, and the Agency has not cited Britthaven for failing to timely implement that Plan of Correction.

Based upon the foregoing Findings of Fact, the undersigned makes the following:

CONCLUSIONS OF LAW

1. A Type A violation is defined by G.S. §131E-129(a)(1) as  
  
a violation by a facility of the regulations, standards, and requirements set forth in G.S. 131E-117, or applicable State or federal laws and regulations governing the licensure or certification of a facility which creates substantial risk that death or serious physical harm to a resident will occur or where such harm has occurred.
2. A Type B violation is defined in G.S. §131E-129(a)(2) as  
  
a violation by a facility of the regulations, standards, and requirements set forth in G.S. 131E-117, or applicable State or federal laws and regulations governing the licensure or certification of a facility which presents a direct relationship to the health, safety or welfare of any resident, but which does not create substantial risk that death or serious physical harm will occur.
3. In determining the amount of the penalty, G.S. §131E-129(c) sets forth the following factors which must be considered by the Agency:
  - (1) The gravity of the violation, including the probability that death or serious physical harm to a resident will result or has resulted; the severity of the actual or potential harm, and the extent to which the provisions of the applicable statutes or regulations were violated;
  - (2) The reasonable diligence exercised by the licensee and efforts to correct violations;
  - (3) The number and type of previous violations committed by the licensee;
  - (4) The amount of assessment necessary to ensure immediate and continued compliance;  
and
  - (5) The number of patients put at risk by the violation.
4. Based upon the foregoing definitions, and the Agency's own internal guidelines set forth in Finding of Fact numbers 28 and 29, the Agency has failed to sustain its burden of showing that the actions of Britthaven created a substantial risk that death or serious physical harm would occur to patients B.C. or W.J., or that such harm occurred. Therefore, the Agency has failed to sustain its burden that a Type A violation was justified.
5. The Agency has sustained its burden of showing that the actions of Britthaven constituted a violation of the regulations, standards and requirements set forth in G.S. 131E-117 or applicable state or federal laws and regulations, which presented a direct relationship to the health, safety, or welfare of patients B.C. and W.J., but which did not create substantial risk that death or serious physical harm would occur to those patients. Therefore, the Agency has sustained its burden of showing that it properly and correctly imposed administrative penalties upon Britthaven for failure to provide adequate care, treatment and services to patients.
6. The Agency's Internal Review Committee's conclusion that the alleged violations by Britthaven warranted two Type B-2 \$50 penalties was a reasonable penalty amount which should have been imposed.

**RECOMMENDED DECISION**

Based upon the foregoing Findings of Fact and Conclusions of Law, it is recommended that the final decision maker order that the administrative penalty imposed by the Licensure Section upon Britthaven be reduced to two Type B-2 \$50 penalties, for a total penalty amount of \$100.

**NOTICE**

The Agency making the final decision in this contested case is required to give each party the opportunity to file exceptions to this recommended decision and to present written arguments to those in the Agency who will make the final decision. G.S. § 150B-36(a). The Agency that will make the final decision in this contested case is the North Carolina Department of Human Resources.

This the 9th day of December, 1992.

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Fred G. Morrison, Jr.  
Administrative Law Judge



*The North Carolina Administrative Code (NCAC) has four major subdivisions of rules. Two of these, titles and chapters, are mandatory. The major subdivision of the NCAC is the title. Each major department in the North Carolina executive branch of government has been assigned a title number. Titles are further broken down into chapters which shall be numerical in order. The other two, subchapters and sections are optional subdivisions to be used by agencies when appropriate.*

**TITLE/MAJOR DIVISIONS OF THE NORTH CAROLINA ADMINISTRATIVE CODE**

<b>TITLE</b>	<b>DEPARTMENT</b>	<b>LICENSING BOARDS</b>	<b>CHAPTER</b>
1	Administration	Architecture	2
2	Agriculture	Auctioneers	4
3	Auditor	Barber Examiners	6
4	Economic & Community Development	Certified Public Accountant Examiners	8
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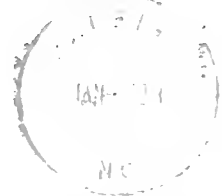
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